Response to Office Action Dated: 11/19/2007

REMARKS

This Amendment and Response is submitted in reply to the Office Action dated August 22, 2007, in which the Examiner:

objected to the Information Disclosure Statement under 37 C.F.R. § 1.98(b) as failing to list all patents, publications, or other information submitted for consideration on form PTO-892;

rejected drawings under 37 C.F.R. § 1.83(a) as failing to show every feature of the invention specified in the claims;

rejected drawings under 37 C.F.R. § 1.84(p)(4) as failing to avoid duplicitous reference character designation;

rejected the specification under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement;

rejected claims 5-7 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement;

rejected claims 1, 3, 4, 7 and 8 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,112,333 to Mazzei; and

rejected claims 5-6 under 35 U.S.C. § 103 as unpatentable over Mazzei '333 in view of U.S. Patent No. 6,490,737 to Mazzei et al.

Applicants respectfully address and/or traverse the rejections below. Claims 1 and 3-8 are currently pending. No Amendments have been made to the Claims.

The Information Disclosure Statement was objected to under 37 C.F.R. § 1.98(b) as failing to list all patents, publications, or other information submitted for consideration on form PTO-892.

For unknown reasons, the USPTO has no Information Disclosure Statement on record. Upon reviewing PAIR, Applicants noticed that the USPTO has not scanned the Information Disclosure Statement for the present application. If the correct images were on record, the Examiner's objections would be without merit. The Applicants respectfully request that this objection be withdrawn.

Response to Office Action Dated: 11/19/2007

A copy of the Information Disclosure Statement that was originally submitted is enclosed, as is a copy of the Postcard indicating that an IDS was submitted with the filing and receipt of which is acknowledged by the USPTO.

The Drawings were rejected under 37 C.F.R. § 1.83(a) for failing to show every feature of the invention specified in the claims, and under 37 C.F.R. § 1.84(p)(4) for using duplications reference character designations. The Examiner asserted numerous deficiencies.

For unknown reasons, the USPTO has incorrect Drawings on record. Rather than having two (2) pages with five (5) figures that depict the present invention, national stage of PCT/EP2003/010719 filed September 26, 2003, PAIR shows five (5) pages with sixteen (16) figures that depict (as shown on the images themselves) PCT/US/09529, which is associated with US Patent No. 6,490,737 to Mazzei et al., the cited prior art. If the correct images were on record, the Examiner's objections would be without merit. The Applicants respectfully request that these rejections be withdrawn.

A copy of the Drawings that were originally submitted is enclosed along with a copy of the Postcard indicating that two (2) pages were submitted, receipt of which is acknowledged by the USPTO.

The Specification was rejected under 35 U.S.C. § 112 as failing to comply with the written description requirement. The Examiner asserted numerous errors in the description provided in light of the drawings.

For unknown reasons, the USPTO also has an incorrect Specification on record. Rather than having the description of the present application, national stage of PCT/EP2003/010719 filed September 26, 2003, PAIR shows PCT/US/09529, which is associated with US Patent No. 6,490,737 to Mazzei et al., the cited prior art. If the correct images were on record, the Examiner's rejection would be without merit. The Applicants respectfully request that these rejections be withdrawn.

A copy of the Specification that was originally submitted is enclosed along with a copy of the Postcard indicating the correct number of pages of the specification submitted, receipt of which is acknowledged by the USPTO.

Response to Office Action Dated: 11/19/2007

Claims 5-7 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserted that the claims were not described in the Specification.

As mentioned above, the Specification on record does not relate the present invention or its claims, but rather to US Patent No. 6,90,737 to Mazzei et al., the cited prior art. The Applicants respectfully request that the rejection be withdrawn.

A copy of the Specification that was originally submitted is enclosed along with a copy of the Postcard indicating that a Marked up copy of the Specification, a Clean copy of the Specification, and a copy of PCT/EP2003/010719 were submitted, receipt of which is acknowledged by the USPTO.

Claim 1 was rejected under 35 U.S.C. § 102(b) as anticipated by US Patent No. 6,112,333 to Mazzei. For a 35 U.S.C. § 102(b) objection to be sustained, a single piece of prior art must show or disclose each and every element of the claimed invention. If any one element of the claimed invention is not shown or disclosed in the prior art, then the anticipation rejection is improper.

Claim 1 recites a headrest for a patient-bearing surface with a rigid support shell and a cushion releasably connectable with the rest shell, wherein the rest shell has an approximately horseshoe-shaped form with a central section for supporting the rear or forehead of a head. Claim 1 further recites that the central section has a support surface of approximately spherical shell shape, with two side sections spaced from one another and that the side support surfaces conform at least approximately to a common cylindrical surface whose axis runs parallel to a line of symmetry of the head support running between the side sections. Claim 1 also recites that the side supports include a cheekbone support that projects in the direction of the other side section.

Mazzei '333 does not show or disclose each and every recitation of Applicants' claim 1. Claim 1 of the present invention recites a <u>headrest</u> for a patient-bearing surface 14, rather than a <u>helmet</u> 10 disclosed by Mazzei. Claim 1 of the present invention recites a <u>horseshoe-shaped form</u> 10. In contrast, Mazzei does not show or disclose a horseshoe-shaped form. Claim 1 of the present invention recites a <u>support surface of approximately spherical shell shape</u> 10 with

Response to Office Action Dated: 11/19/2007

two cylindrical side sections 16. Mazzei does not show or disclose such a structure; instead, Mazzei discloses a helmet 10 with flat frontal surface 41 and flat side surface 43. Thus, Mazzei fails to disclose the patient-bearing surface rest shell of horseshoe-shaped form with two side sections. Accordingly, Applicants respectfully submit that the rejection of claim 1 under 35 U.S.C. § 102(b) as anticipated by Mazzei is improper for at least these reasons, and should be withdrawn.

Claims 3, 4, 7 and 8 were also rejected under 35 U.S.C. § 102(b) as anticipated by Mazzei '333. These claims all depend, directly or indirectly from Applicants' claim 1 and include additional recitations thereto. Additionally, claim 4 recites a headrest with support cushions having at least two stick pins designed for insertion into the bores in the rest shell. Mazzei '333 does not show or disclose the use of stick pins to connect support cushions to an outer shell. Claim 7 recites a headrest connected to a fastening block for holding it to a profiled rail. Mazzei '333 does not show or disclose a rail-based mounting system or the use of fastening blocks. Accordingly, Applicants respectfully submit that the rejection of claims 3, 4, 7 and 8 under 35 U.S.C. § 102(b) as anticipated by Mazzei is improper for at least the same reasons stated in connection with claim 1, and should be withdrawn.

Claims 5-6 were rejected under 35 U.S.C. § 103(a) as being unpatentable over US Patent No. 6,112,333 to Mazzei in view of US Patent No. 6,490,737 to Mazzei et al. The Examiner asserts that Mazzei '333 discloses a headrest for a patient-bearing surface with rigid-support shell and a cushion releasably connected with the rest shell, and Mazzei '737 teaches a device for protecting a patient's head wherein the device includes stick pins as part of a helmet. For a 35 U.S.C. § 103(a) objection to be sustained, the prior art references, either independently or in combination, must teach or suggest the claimed invention to one having ordinary skill in the art.

Claims 5-6 depend directly from claim 1 and include additional recitations thereto. As discussed, Mazzei '333 does not teach or suggest each and every recitation of Applicants' claim 1. Claim 1 of the present invention recites a

Response to Office Action Dated: 11/19/2007

headrest for a patient-bearing surface 14, rather than a helmet 10 as taught by Mazzei '333. Claim 1 of the present invention recites a horseshoe-shaped form 10. In contrast, Mazzei '333 does not teach or suggest a horseshoe-shaped form. Claim 1 of the present invention recites a support surface of approximately spherical shell shape 10 with two cylindrical side sections 16. Mazzei '333 does not teach or suggest such a structure; instead, Mazzei '333 teaches a helmet 10 with flat frontal surface 41 and flat side surface 43. Additionally, claim 5 recites a headrest with support cushions connected to the rest shell by stick pins each having a cylindrical shaft which cylindrical shaft has an elastically resilient band with an external diameter slightly larger than the diameter of the bores in the rest shell. Mazzei '333 does not teach or suggest the use of stick pins of any shape or design. Claim 6 recites a headrest divided into two mirror image similar partial supports. Mazzei '333 does not teach or suggest a bifurcation of the design. Thus, Mazzei '333 fails to teach or suggest the patient-bearing surface rest shell of horseshoe-shaped form with two side sections.

Mazzei '737 does not add to the teachings of Mazzei '333, at least in that Mazzei '737 does not teach or suggest a headrest for a patient-bearing surface, a horseshoe-shaped form, or a support surface of approximately spherical shell shape with two cylindrical side sections. Additionally, Mazzei '737 does not teach or suggest the use of stick pins, or the division of the headrest into two mirror image partial supports. Instead, Mazzei '737 teaches an alternate configuration of the Mazzei '333 helmet that includes a mounting plate structure as well as additional features such as heated cushions and viewing mirrors. Thus, neither Mazzei '333 nor Mazzei '737, nor the combination thereof teaches or suggests each and every recitation of Applicants' amended claim 1. Accordingly, Applicants respectfully submit that the rejection of dependent claims 5-6 under 35 U.S.C. § 103(a) is improper for at least these reasons, and should be withdrawn.

Applicants enclose a copy of the Information Disclosure Statement, Drawings, Specifications submitted on May 13, 2005 to the USPTO. Also, a copy of the Preliminary Amendment, the English Translation document, the Marked up copy of the specification, the Transmittal letter, PCT/EP2003/010719, the

Application Serial No. 10/534,837

Office Action Dated: 08/22/2007

Response to Office Action Dated: 11/19/2007

Search Report, and the IPER are enclosed. Lastly, we also enclose a copy of the Returned Receipt Postcard that verifies the submission of the above listed materials.

Having addressed and/or traversed each and every rejection, Applicants respectfully request that the rejections of claims 1 and 3-8 be withdrawn, and that these claims be passed to issue.

Additionally, Applicants request that proper Specification, Drawing, and Information Disclosure Statement be made of record.

Applicants believe no additional fees are due in connection with this Response. In the event any additional fees are deemed necessary, authorization is hereby granted to charge any such fees to Deposit Account No. 13-0235.

Respectfully submitted,

 $By_{\underline{}}$

Marina F. Cunningham Registration No. 38,419

Attorney for the Applicants

McCORMICK, PAULDING & HUBER LLP CityPlace II, 185 Asylum Street Hartford, CT 06103-3402 (860) 549-5290

Ser/Pat/TM No. NEW NOT! Apolo Date Received: Inventor Name(s). Piontek Atty/Secretary MFC/Ca MAY 27 2005 Hon. Commissioner of Patents/Trademarks Rec'd Portriol Caulding Please acknowledge receipt of the attachments by stamping the date received in the space indicated and returning this card to the addressee. McCormick, Paulding & Huber LLP ☐ Specification - # of pages..... Transmittal letter Check - \$...,130.00.... □ Claims - # of pages..... Drawings - # of sheets ... Amendment - PICLIM. AIDS and PTO/SB/08A/YY9
Copies of IDS citations
Maintenance Fee ☐ Issue Fee/Publication Fee English translation document □ Extension of Time ☐ Assignment ADS A copy of PCT/EP2003/010719 A copy of Search Report Marked up copy of specification/elains
Clean copy of specification/elains
Dec/POA

PTO-1390 (Rev. 02-2005) Approved for use through 3/31/2007. OMB 0651-0021

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL LETTER TO THE UNITED STATES ATTTORNEY'S DOCKET NUMBER 2619-0038WOUS DESIGNATED/ELECTED OFFICE (DO/EO/US) U.S. APPLICATION NO. (If known, see 37 CFR 1.5) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 INTERNATIONAL APPLICATION NO PCT/EP2003/010719 INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED 26 Sept. 2003 18 Nov. 2002 TITLE OF INVENTION HEADREST FOR A PATIENT-BEARING SURFACE APPLICANT(S) FOR DO/EO/US Manfred Piontek Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. The US has been elected (Article 31). A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). b. has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). 6. An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). 4 Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. ~ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. L An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: 11. An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. J An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. 🛂 A preliminary amendment. An Application Data Sheet under 37 CFR 1.76. A substitute specification. A power of attorney and/or change of address letter. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825. A second copy of the published International Application under 35 U.S.C. 154(d)(4). A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

20. Other items or information: Courtesy Copies of: International Appln. No. PCT/EP2003/010719, International Search Report,

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Page 1 of 2

PTO-1390 (Rev. 02-2005)
Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)
INTERNATIONAL APPLICATION NO. ATTORNEY'S DOOVET AND THE PROPERTY OF COMMERCE.

	1011 140. (II KIIOWI	1, 3 00 37 CFK 1.5	PCT/EP20		2619-0038			
The foll	The following fees have been submitted					CALCULATIONS PTO USE ONL		
21. 🔽 Basi	ic national fee	\$ 300.00						
If International p PCT Article 3:	3(1)-(4)		red by USPTO and all claims	\$100	\$ 200.00			
Search fee (37 C Internatio International Sea	rch fee FR 1.445(a)(2)) h nal Searching Aut rch Report prepar is	\$ 500.00						
	TOTAL OF 21, 22	2 and 23 =			\$ 1000.00			
sequence lis	sting or computer i	oroaram listina file	in paper over 100 sheets (ex d in an electronic medium). paper or fraction thereof.	ccluding				
Total Sheets	Extra Sheets		additional 50 or fraction p to a whole number)	RATE				
12 - 100 =	/50 =			x \$250	\$			
Surcharge of \$13 claimed priority d	0.00 for furnishing ate (37 CFR 1.492	the oath or decla (e)).	ration later than 30 months fo		\$ 130.00			
CLAIMS	NUMB	ER FILED	NUMBER EXTRA	RATE	\$			
Total claims		7 - 20 =		× \$ 50	\$			
Independent clair	ns	1 -3=		× \$200	\$			
MULTIPLE DEPE	NDENT CLAIM(S) (if applicable)		+ \$360	\$			
			TOTAL OF ABOVE	CACULATIONS =	\$ 1130.00			
Applicant clai	ms small entity st	atus. See 37 CFR	1.27. Fees above are reduce	ed by 1/2.	\$			
				SUBTOTAL =	\$ 1130.00			
Processing fee of claimed priority da	\$130.00 for fumis ate (37 CFR 1.492	shing the English t	ranslation later than 30 month	ns from the earliest	\$			
			TOTAL	NATIONAL FEE =	\$ 1130.00			
Fee for recording by an appropriate	the enclosed assi cover sheet (37 C	gnment (37 CFR CFR 3.28, 3.31). \$	1.21(h)). The assignment mus 40.00 per property	t be accompanied +	\$			
			TOTAL FE	ES ENCLOSED =	\$ 1130.00			
					Amount to be refunded:	\$.		
					Amount to be charged:	\$		
a. A check	in the amount of	\$ _1130.00	to cover the above	re fees is enclosed.	chargeo.			
b. Please of A duplic	charge my Deposi ate copy of this sh	t Account No	in the amount of \$	to co	ver the above fees.			
c. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit t Account No. 13-0235 A duplicate copy of this sheet is enclosed.								
d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.								
NOTE: Where an and granted to re	appropriate time	limit under 37 C	FR 1.495 has not been met, n to pending status.	a petition to revive	(37 CFR 1.137(a) or (b)	must be filed		
SEND ALL CORR			. •	11	• - /)			
Customer No.		aring of	u					
Marina F. Cun	ningham			SIGNATURE				
McCormick, Pa			,	Marina F. Cunning	ham, Date: May 13, 2	2005		
185 Asylum St Hartford, CT 0	reet, CityPlace	e II		NAME				
, iditioid, OT (0100-0402			Registration No.				
5000000000	390 (REV. 02-2005)		Dogo 2 of 2	REGISTRATIC	N NUMBER			

Courtesy Copies of:

International Application No. PCT/EP2003/010719 International Search Report International Preliminary Examination Report

Attorney Docket No. 2619-0038 WOUS

HEADREST FOR A PATIENT-BEARING SURFACE

"EXPRESS MAIL" MAILING LABEL
NUMBER EV 331995172 US
DATE OF DEPOSIT May 13, 2005 I HEREBY CERTIFY THAT THIS PAPER OR FEE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE "EXPRESS MAIL POST OFFICE TO ADDRESSE" SERVICE UNDER 37 CFR 1.10 ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE COMMISSIONER FOI PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.
Christine Rounds (TYPED OR PRINTED NAME OF PERSON MAILING PAVEL) OR FEE) (SIGNATURE OF PERSON MAILING PAPER OR FEE)

(19) Weltorganisation für geistiges Eigentum Internationales Büro



(43) Internationales Veröffentlichungsdatum 3. Juni 2004 (03.06.2004)

PCT

(10) Internationale Veröffentlichungsnummer WO 2004/045481 A1

(51) Internationale Patentklassifikation⁷: 7/07, A47C 31/00

A61G 13/12,

(21) Internationales Aktenzeichen:

PCT/EP2003/010719

(22) Internationales Anmeldedatum:

26. September 2003 (26.09.2003)

(25) Einreichungssprache:

Deutsch

(26) Veröffentlichungssprache:

Deutsch

_

(30) Angaben zur Priorität: 202 17 825.0 18. No

18. November 2002 (18.11.2002) DE

(71) Anmelder (für alle Bestimmungsstaaten mit Ausnahme von US): MAQUET GMBH & CO. KG [DIFIDE]: Kehler Strasse 31, 76437 Rastatt (DE).

(72) Erfinder; und

(75) Erfinder/Anmelder (nur für US): PIONTEK, Munfred [DE/DE]; Karlstrasse 63, 76137 Karlsruhe (Dl.).

(74) Anwälte: SCHAUMBURG, Karl-Heinz usw.: Postfach 86 07 48, 81634 München (DE).

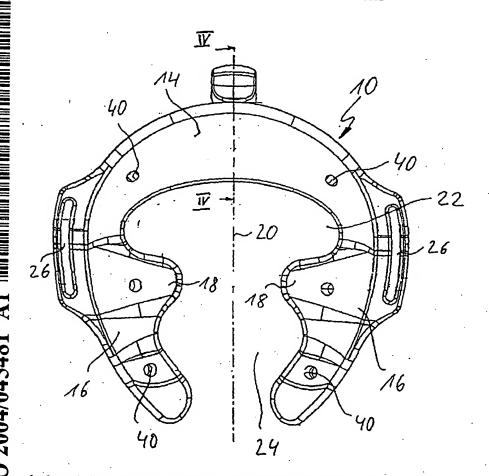
(81) Bestimmungsstaaten (national): JP, US.

(84) Bestimmungsstaaten (regional): europäisches Patent (AT. BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, I'R, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR).

[Fortsetzung auf der nächsten Seite]

(54) Title: HEADREST FOR A PATIENT-BEARING SURFACE

(54) Bezeichnung: KOPFSTÜTZE FÜR PATIENTENLAGERFLÄCHE



und mit zwei einen Abstand voneinander aufweisenden Seitenabschnitten

(57) Abstract: A headrest for a patient-bearing surface, having an approximately horseshoe-shaped design and comprising a central section (14) for supporting the back of the head or the forehead. the bearing surface thereof being at least approximately spherical shell-shaped, also comprising two side sections (16) which are arranged at a distance from each other and whose bearing surfaces are adapted at least approximately in relation to a common cylindrical surface, and whose axis is parallel to a symmetrical line (20) of the headrest extending between the side surfaces (16). A cheekbonc support (18), which respectively protrudes in the direction of the other respective side section (16), is provided on the side sections (16).

(57) Zusammenfassung: Eine Kopfstütze für eine Patientenlagerfläche hat eine annähernd hufeisenförmige Gestalt mit einem zum Unterstützen des Hinterkopfes oder der Stirn bestimmten zentralen Abschnitt (14), dessen Auflagefläche mindestens annähernd kugelschalenförmig ist,

[Fortsetzung auf der nächsten Seite]

Veröffentlicht:

mit internationalem Recherchenbericht

Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

^{(16),} deren Auflageflächen mindestens annähernd einer gemeinsamen Zylinderfläche angepasst sind, deren Achse parallel zu einer zwischen den Seitenabschnitten (16) verlaufenden Symmetrielinie (20) der Kopfstütze ist, wobei an den Seitenabschnitten (16) jeweils eine in Richtung auf den jeweils anderen Seitenabschnitt (16) vorspringende Jochbeinstütze (18) ausgebildet ist.

Kopfstütze für Patientenlagerfläche

Die Erfindung betrifft eine Kopfstütze für eine Patientenlagerfläche, insbesondere an Operationstischen.

Aus der US 6,276,012 B2 ist eine Kopfstütze bekannt, die aus einem U-förmigen Teil und einem zwischen den U-Schenkeln liegenden plattenförmigen Abschnitt besteht. In der Rückenlage wird der Kopf des Patienten von beiden Teilen unterstützt. In der Bauchlage wird das plattenförmige Teil weggeklappt, so daß der Kopf des Patienten mit der Stirn auf dem Mittelsteg des U aufliegt und zumindest Mund und Nase des Patienten frei liegen. Die Kopfstütze insgesamt ist im wesentlichen eben ausgebildet und gepolstert. Sowohl in der Rückenlage als auch in der Bauchlage ist der Kopf seitlich nicht abgestützt.

Aus der US-A-6,042,184 ist eine Ruheliege bekannt, die mit einer plattenförmigen Kopfstütze versehen ist. In der plattenförmigen Kopfstütze ist eine Öffnung ausgebildet, die von einem kreisringförmigen, nicht ganz geschlossenen Polster umgeben ist, das auf der Platte beispielsweise mit Druckknöpfen befestigt werden kann. Auch hier kann der Kopf einer Person nicht nur in der Rückenlage sondern auch in der Bauchlage abgestützt werden, wobei das Gesicht frei liegt. Die Kopfstütze ist jedoch nicht ausreichend an die menschliche Kopfform angepaßt und ungeeignet, den Kopf eines Patienten während einer Operation, bei welcher der Patient längere Zeit regungslos gehalten werden muß, so abzustützen, daß der Patient keinen Schaden nimmt, beispielsweise durch Druckstellen oder dergleichen.

Der Erfindung liegt die Aufgabe zugrunde, eine Kopfstütze der eingangs genannten Art anzugeben, die es ermöglicht, den Kopf in einer gewünschten Position sowohl in

der Rückenlage als auch der Bauchlage des Patienten sicher und für den Patienten schonend zu unterstützen.

Zur Lösung dieser Aufgabe hat die erfindungsgemäße Kopfstütze eine annähernd hufeisenförmige Gestalt mit einem zum Unterstützen des Hinterkopfes oder der Stirn bestimmten zentralen Abschnitt, dessen Auflagefläche mindestens annähernd kugelschalenförmig ist, und mit zwei einen Abstand voneinander aufweisenden Seitenabschnitten, deren Auflageflächen mindestens annähernd einer gemeinsamen Zylinderfläche angepaßt sind, deren Achse parallel zu einer zwischen den Seitenabschnitten verlaufenden Symmetrielinie der Kopfstütze ist, wobei an den Seitenabschnitten jeweils eine in Richtung auf den jeweils anderen Seitenabschnitt vorspringende Jochbeinstütze ausgebildet ist.

Die erfindungsgemäße Kopfstütze ist an die spezielle Form des menschlichen Kopfes angepaßt und unterstützt den Kopf an den für eine solche Unterstützung geeigneten Flächen des Schädels, nämlich dem Hinterkopf oder der Stirn sowie den Wangenknochen. Durch die kugelschalenförmige bzw. zylindrische Wölbung der Abschnitte ist der Kopf so gebettet, daß er nicht nach der Seite umfallen kann. Die Jochbeinstützen an den Seitenabschnitten ermöglichen einerseits eine gute Unterstützung des Gesichtes in der Bauchlage des Patienten, wobei dennoch die Augenpartie sowie Mund und Nase für das Atmen bzw. die Beatmung sowie das Ansetzen einer Narkosemaske oder anderer Hilfsmittel frei bleiben. Durch die anatomisch gerechte Form der erfindungsgemäßen Kopfstütze wird der Auflagedruck des Kopfes großflächiger über die Abschnitte der Kopfstütze verteilt, so daß die lokale Belastung vermindert wird und damit auch bei längeren Operationen Druckstellen am Kopf, insbesondere im Gesicht vermieden werden können.

Vorzugsweise besteht die Kopfstütze aus einer starren Stützschale und einem mit dieser lösbar verbindbaren Auflagepolster. Im Gegensatz zu herkömmlichen Kopfstützen, bei denen zur seitlichen Abstützung des Kopfes das Polster sehr dick gemacht werden muß, d.h. der Kopf relativ weit in das Polster einsinkt, kann bei der erfindungsgemäßen Lösung wegen der anatomisch korrekten Form der Kopfstütze das Auflagepolster dünner gemacht werden. Die Stützschale ist zweckmäßigerweise

aus Kunststoff hergestellt, was sowohl die Herstellung beispielsweise im Spritzgußverfahren als auch die Pflege der Stützschale im täglichen Betrieb erleichtert.

Vorzugsweise hat das Auflagepolster an einer der Stützschale zugewandten Seite mindestens zwei Steckstifte, die zum Eingriff in die Stützschale durchsetzende Bohrungen bestimmt sind. Auf diese Weise kann das Auflagepolster schneil und sicher mit der Stützschale verbunden und wieder von dieser gelöst werden. Sowohl die Bohrungen als auch die Steckstifte sind einfach und sicher zu reinigen. Um ein ungewolltes Lösen des Auflagepolsters von der Stützschale zu vermeiden, kann es zweckmäßig sein, wenn die Steckstifte an einem zylindrischen Schaft jeweils einen elastisch nachgiebigen Bund haben, dessen Durchmesser gegenüber dem Bohrungsdurchmesser geringfügig größer ist, so daß die Steckstifte nur mit einem gewissen Widerstand durch die Bohrungen in der Stützschale gedrückt bzw. herausgezogen werden können.

Die erfindungsgemäße Kopfstütze kann einteilig ausgebildet sein oder auch entlang ihrer Symmetrielinie in zwei spiegelbildlich gleiche Teilstützen unterteilt sein. Letztere Ausführungsform ermöglicht eine gewisse Anpassung der Kopfstütze an unterschiedlich große Köpfe.

Zur Verbindung der Kopfstütze mit der Patientenlagerfläche kann die Kopfstütze bzw. jede Teilstütze in an sich bekannter Weise mit einem Befestigungskloben zur Halterung an einer Profilschiene verbunden sein, die ihrerseits an einer Patientenlagerfläche oder einer mit dieser verbundenen Halterung befestigt ist. Um sicherzustellen, daß der Patient während einer Operation den Kopf nicht bewegt, kann an dem Außenrand jedes Seitenabschnittes eine Öse zur Befestigung eines Bandes ausgebildet sein, mit dem der Patientenkopf auf der Kopfstütze fixiert werden kann.

Weitere Merkmale und Vorteile der Erfindung ergeben sich aus der folgenden Beschreibung, welche in Verbindung mit den beigefügten Zeichnungen die Erfindung anhand von Ausführungsbeispielen erläutert. Es zeigen:

- Figur 1 eine Draufsicht auf die Stützschale einer ersten Ausführungsform der erfindungsgemäßen Kopfstütze,
- Figur 2 eine Seitenansicht einer mit einem Auflagepolster und einem Fixierband versehenen Kopfstütze,
- Figur 3 eine perspektivische Unteransicht eines für eine Stützschale gemäß Figur 1 bestimmten Auflagepolsters,
- Figur 4 einen Teilschnitt durch die Stützschale entlang Linie IV-IV in Figur 1 und
- Figur 5 eine der Figur 1 entsprechende Draufsicht auf eine Stützschale einer zweiten Ausführungsform der erfindungsgemäßen Kopfstütze.

Die in den Figuren 1 bis 4 dargestellte Kopfstütze hat eine im wesentlichen hufeisenförmige Gestalt und umfaßt eine allgemein mit 10 bezeichnete Stützschale und ein dieser Stützschale in seiner Form angepaßtes Auflagepolster 12. Die Stützschale hat einen zentralen Abschnitt 14, der zur Unterstützung des Hinterkopfes eines Patienten (Rückenlage) oder der Stirn (Bauchlage) bestimmt ist. Dieser mittlere Abschnitt 14 ist auf seiner dem Betrachter der Figur 1 zugewandten Ober- oder Innenseite mindestens annähernd kugelschalenförmig ausgebildet. An den zentralen Abschnitt 14 schließen sich zwei Seitenabschnitte 16 an, die sich mit ihren freien Enden einander annähern und jeweils einen in Richtung auf den jeweils anderen Seitenabschnitt vorspringenden Abschnitt 18 haben, der eine Jochbeinstütze bildet, d.h. das Gesicht eines auf dem Bauch liegenden Patienten im Bereich der Wangenknochen unterstützt. Die Seitenabschnitte 16 sind annähernd an eine gemeinsame Zylinderfläche angepaßt, deren Achse parallel zu der zwischen den beiden Seitenabschnitten 16 verlaufenden Symmetrieachse 20 der Kopfstütze verläuft. Die zentrale Aussparung der Stützschale 10 umfaßt einen dem zentralen Abschnitt 14 nahen Bereich 22 entsprechend der Augenpartie des **Patientengesichtes** und einen der. Mundpartie des Patientengesichtes entsprechenden Bereich 24. Durch die Anpassung der Stützschale 14 an die

anatomische Form des Kopfes wird einerseits eine bessere seitliche Abstützung und andererseits eine großflächigere Auflage des Kopfes auf der Kopfstütze erreicht, wodurch wiederum die lokale Druckbelastung und damit die Gefahr der Bildung von Druckstellen am Kopf des Patienten vermindert wird.

An den Außenrändern der Seitenabschnitte 16 ist jeweils eine Öse 26 vorgesehen, durch die ein Band 28 gezogen werden kann, mit dem der Kopf eines Patienten auf der Kopfstütze fixiert werden kann. Das Band 28 wird dabei durch die Öse 26 durchgezogen, wonach die Enden des Bandes umgeschlagen und beispielsweise mittels eines Klettverschlusses festgelegt werden, wie dies in Figur 2 angedeutet ist. Auf der Innenseite des Bandes befindet sich ein Polster 30 über das das Band 28 an dem Kopf des Patienten anliegt.

Das mit der Stützschale gemäß Figur 1 zu verbindende Auflagepolster ist in Figur 3 dargestellt. Es hat eine der Form der Stützschale 10 angepaßte Gestalt mit einem zentralen Abschnitt 32 und Seitenabschnitten 34. An seiner der Stützschale 10 zugewandten Seite trägt das Auflagepolster Steckstifte 36, die im wesentlichen zylindrisch ausgebildet sind und in einer umlaufenden Nut einen O-Ring 38 tragen. Die Steckstifte 36 werden in in der Stützschale 10 vorgesehene Bohrungen 40 gesteckt, wobei die Abmessungen der Bohrungen 40 und der Steckstifte 36 so gewählt sind, daß die O-Ringe dem Einstecken und Herausziehen der Steckstifte 36 in die bzw. aus den Bohrungen 40 einen gewissen Widerstand entgegensetzen. Das Auflagepolster 12 kann aber auf diese Weise rasch mit der Stützschale 10 verbunden bzw. von dieser gelöst werden, so daß die Stützschale 10 und das Auflagepolster 12 problemlos und hygienisch einwandfrei gereinigt werden können.

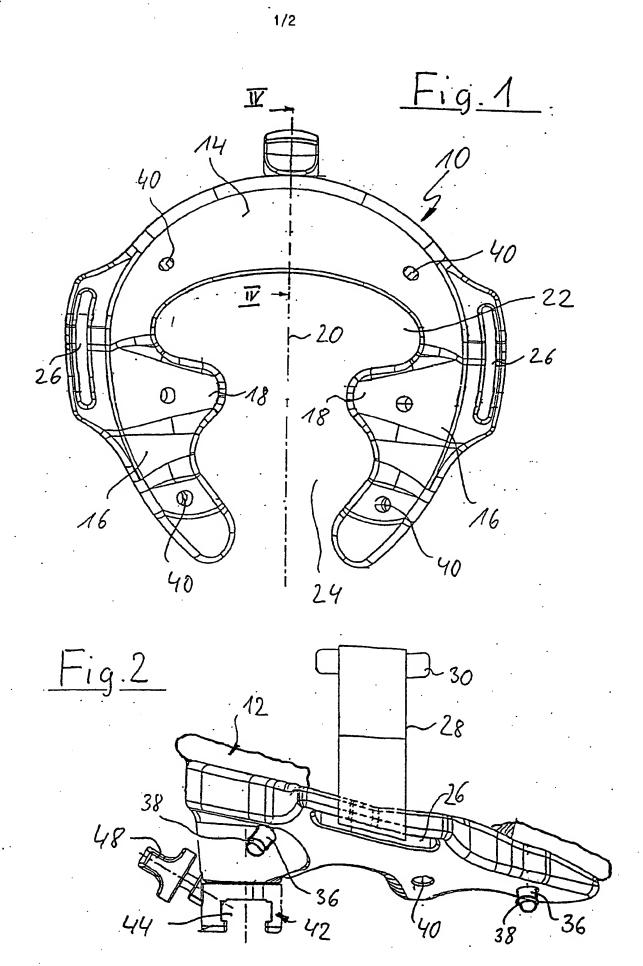
Figur 4 zeigt einen mit der Stützschale verbundenen Befestigungskloben 42, der eine Profilöffnung 44 hat, mit der er auf eine Profilschiene aufschiebbar ist und der mittels einer Schraube 46 an der Stützschale 10 befestigt ist. Mittels einer Klemmschraube 48 kann der Kloben 42 und damit die gesamte Kopfstütze auf der Profilschiene festgelegt werden.

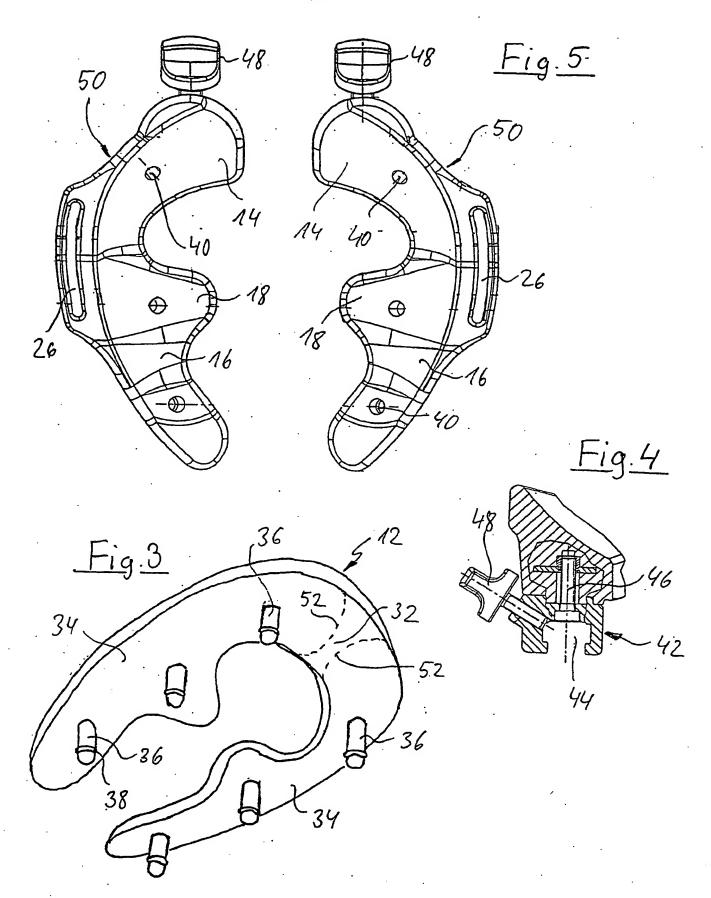
Figur 5 zeigt eine zweiteilige Stützschale für eine zweiteilige Kopfstütze. Die beiden Teilschalen 50 sind bezüglich der Symmetrielinie 20 spiegelsymmetrisch zueinander ausgebildet und entsprechen in allen Einzelheiten den entsprechenden Abschnitten der einteiligen Stützschale gemäß Figur 1 mit der Ausnahme, daß jede Teilschale 50 mit einem Befestigungskloben 42 versehen ist. Das zugehörige Auflagepolster ist ebenso unterteilt wie die Stützschale, wie dies in Figur 3 durch die gestrichelten Linien 52 angedeutet ist. Die Ausführungsform gemäß Figur 5 bietet die Möglichkeit, durch Veränderung des Abstandes zwischen den beiden Teilstützen die Kopfstütze an die Größe des abzustützenden Kopfes anzupassen.

Ansprüche

- 1. Kopfstütze für eine Patientenlagerfläche, gekennzeichnet durch eine annähernd hufeisenförmige Gestalt mit einem zum Unterstützen des Hinterkopfes oder der Stirn bestimmten zentralen Abschnitt (14), dessen Auflagefläche mindestens annähernd kugelschalenförmig ist, und mit zwei einen Abstand voneinander aufweisenden Seitenabschnitten (16), deren Auflageflächen mindestens annähernd einer gemeinsamen Zylinderfläche angepaßt sind, deren Achse parallel zu einer zwischen den Seitenabschnitten (16) verlaufenden Symmetrielinie (20) der Kopfstütze ist, wobei an den Seitenabschnitten (16) jeweils eine in Richtung auf den jeweils anderen Seitenabschnitt (16) vorspringende Jochbeinstütze (18) ausgebildet ist.
- 2. Kopfstütze nach Anspruch 1, dadurch **gekennzeichnet**, daß sie eine starre Stützschale (10) und ein mit dieser lösbar verbindbares Auflagepolster (12) umfaßt.
- 3. Kopfstütze nach Anspruch 2, dadurch **gekennzeichnet**, daß die Stützschale (10) aus Kunststoff besteht.
- 4. Kopfstütze nach Anspruch 2 oder 3, dadurch gekennzeichnet, daß das Auflagepolster(12) an seiner der Stützschale (10) zugewandten Seite mindestens zwei Steckstifte (36) trägt, die zum Eingriff in die Stützschale (10) durchsetzende Bohrungen (40) bestimmt sind.
- Kopfstütze nach Anspruch 4, dadurch gekennzeichnet, daß die Steckstifte (36) jeweils einen zylindrischen Schaft haben, der einen elastisch nachgiebigen Bund (38) mit einem gegenüber dem Bohrungsdurchmesser geringfügig größeren Außendurchmesser hat.
- 6. Kopfstütze nach einem der Ansprüche 1 bis 5, dadurch **gekennzeichnet**, daß sie entlang ihrer Symmetrielinie (20) in zwei spiegelbildlich gleiche Teilstützen (50) unterteilt ist.

- 7. Kopfstütze nach einem der Ansprüche 1 bis 6, dadurch **gekennzeichnet**, daß die Kopfstütze bzw. jede Teilstütze mit einem Befestigungskloben (42) zu ihrer Halterung an einer Profilschiene verbunden ist.
- 8. Kopfstütze nach einem der Ansprüche 1 bis 7, dadurch **gekennzeichnet**, daß an dem Außenrand jedes Seitenabschnittes (16) eine Öse (26) zur Befestigung eines zum Fixieren des Patientenkopfes auf der Kopfstütze bestimmten Bandes (28) ausgebildet ist.





A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61613/12 A61G7/07

A47C31/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61G A61F A47C A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

Category •	Citation of document with indication	
	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01 76403 A (MAZZEI WILLIAM) 18 October 2001 (2001-10-18)	1-5,8
Y	page 3 -page 2, line 10 page 16, line 13 - line 23 page 18, line 7 - line 12 page 32, line 9 -page 33, line 9; figures 1,7-11	6,7
(\	US 6 374 441 B1 (BEGELL SUZANNE) 23 April 2002 (2002-04-23) column 2, line 45 -column 3, line 15; figures	1 3,6,7
·	-/	

Further documents are listed in the continuation of box C.	χ Patent family members are listed in annex.
Special categories of cited documents: 'A' document defining the general state of the art which is not considered to be of particular relevance 'E' earlier document but published on or after the international filing date 'L' document which may throw doubts on priority claim(s) or which is each back the second or second.	 *T* later document published after the International filing date or priority date and not in conflict with the application but clied to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
Clation or other special reason (as specified) Condition or other special reason (as specified) Condition or other means	'Y' document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. '&' document member of the same patent family
Date of the actual completion of the international search 5 January 2004	Date of mailing of the international search report 13/01/2004
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NI. – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo ni, Fax: (+31-70) 340-3016	Authorized officer Cametz, C



PCT/EP 03/10719

C.(Continu	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	PCT/EP 0	3/10719
Calegory •	Citation of document, with indication, where appropriate, of the relevant passages		Indiana i
	, , , , , , , , , , , , , , , , , , ,		Relevant to claim No.
Y	WO 00 47155 A (DINKLER CHARLES E ;OHIO MED INSTR CO INC (US)) 17 August 2000 (2000-08-17) page 21, line 5 - line 19 page 22, line 15 -page 23, line 5; figures 11,13		6,7
	WO 97 25956 A (DELATTRE OLIVIER) 24 July 1997 (1997-07-24) page 4, line 12 - line 16; figure 1		7
		·	
	·		
			j
	· ·		
AT 424 T-1	(continuation of second sheet) (July 1892)		

ENATIONAL SEARCH REPORT

mation on patent family members

PCT/EP 03/10719

Patent document cited in search report	1	Publication date		Patent family member(s)	Publication date
WO 0176403	A	18-10-2001	WO AU CA EP	0176403 A1 4224500 A 2404653 A1 1280428 A1	18-10-2001 23-10-2001 18-10-2001 05-02-2003
US 6374441	B1	23-04-2002	NONE		
WO 0047155	A	17-08-2000	AU CA EP JP WO US	2992100 A 2362562 A1 1152727 A1 2002536119 T 0047155 A1 2002032927 A1	29-08-2000 17-08-2000 14-11-2001 29-10-2002 17-08-2000 21-03-2002
W0 9725956	Α	24-07-1997	WO EP JP	9725956 A1 0814742 A1 11502146 T	24-07-1997 07-01-1998 23-02-1999

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES IPK 7 A61G13/12 A61G7/07 A47C31/00

Nach der Internationalen Patentklassifikation (IPK) oder nach der nationalen Klassifikation und der IPK

B. RECHERCHIERTE GEBIETE

Recherchlerter Mindestprüfstoff (Klassiffikationssystem und Klassiffikationssymbole) IPK 7 A61G A61F A47C A61B

Recherchlerte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der Internationalen Recherche konsultierte elektronische Dalenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)

EPO-Internal

Kategorie*	Bezelchnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
χ	WO 01 76403 A (MAZZEI WILLIAM)	
	18. Oktober 2001 (2001-10-18)	1-5,8
Υ	Seite 3 -Seite 2, Zeile 10	
	Seite 16, Zeile 13 - Zeile 23	6,7
	Seite 18, Zeile 7 - Zeile 12	
I	Seite 32, Zeile 9 -Seite 33, Zeile 9.	
	Abbildungen 1,7-11	•
(11C C 27A 444 27 (27)	
,	US 6 374 441 B1 (BEGELL SUZANNE)	1
. I	23. April 2002 (2002-04-23)	•
`	Spalte 2, Zeile 45 -Spalte 3, Zeile 15; Abbildungen	3,6,7
1		
1	-/	
1		•
ŀ		
1	·	
1		

Weitera Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen	X Siehe Annang Patentfamilie		
Besondere Kategorien von angegebenen Veröffentlichungen :	177 C- 51 11 - 77 - 11 - 1		
'A' Veröffentlichung, die den allgemeinen Stand der Technik definiert, aber nicht als besonders bedeutsam anzusehen ist	T Spätere Veröffentlichung, die nach dem internationalen Anmeldedatum oder dem Prioritätsdatum veröffentlicht worden ist und mit der Anmeldung nicht kollidiert, sondern nur zum Verständnis des der Erfügtige zuradelte.		
"E" älteres Dokument, das jedoch erst am oder nach dem internationalen Anmeldedatum veröffentlicht worden ist	Theorie angegeben ist		
"L" Veröffentlichung, die geeignet ist, einen Prioritätsanspruch zweifelhaft er- scheinen zu lassen, oder durch die das Veröffentlichungsdatum einer anderen im Recherchenbericht genannten Veröffentlichung belegt werden soll oder die aus einem anderen besonderen Grund bei get werden.	"X" Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann allein aufgrund dieser Veröffentlichung nicht als neu oder auf erfinderischer Tätigkeit beruhend betrachtet werden		
ausgeführt)	kann nicht als auf erfinderischer Tällgreit bereite beanspruchte Erfindung		
O Veröffentlichung, die sich auf eine mündliche Offenbarung, eine Benutzung, eine Ausslellung oder andere Maßnahmen bezieht *P* Veröffentlichung, die vor dem internationalen Anmeldedatum, aber nach	werden, wenn die Veröffentlichung mit einer oder mehreren anderen Veröffentlichungen dieser Kategorie in Verbindung gebracht wird und diese Verbindung für einen Fachmann naheilegend ist *&* Veröffentlichung, die Mitglied derselben Patentfamilie ist		
som beautspruchten Flioritatsdatum veröffentlicht worden ist			
Datum des Abschlusses der Internationalen Recherche	Absendedatum des internationalen Recherchenberichts		
5. Januar 2004	13/01/2004		
Name und Postanschrift der Internationalen Recherchenbehörde Europäisches Patentami, P.B. 5818 Patentiaan 2	Bevollmächtigter Bediensteler		
Tel. (+31-70) 340-2040, Tx. 31 651 epo ni, Fax: (+31-70) 340-3016	Cametz, C		
Formblatt PCT/ISA/210 (Blatt 2) (Juli 1992)			



PCT/EP 03/10719

Kategorie*	LING) ALS WESENTLICH ANGESEHENE UNTERLAGEN		
-zeriañoue.	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden	Teile	Betr. Anspruch Nr.
Y	WO 00 47155 A (DINKLER CHARLES E ;OHIO MED INSTR CO INC (US)) 17. August 2000 (2000-08-17) Seite 21, Zeile 5 - Zeile 19 Seite 22, Zeile 15 -Seite 23, Zeile 5; Abbildungen 11,13		6,7
A	WO 97 25956 A (DELATTRE OLIVIER) 24. Juli 1997 (1997-07-24) Seite 4, Zeile 12 - Zeile 16; Abbildung 1		7
			*
	/210 (Fortsatzung von Blalt 2) (كاناً 1992)		

INTERNATIONAL RECHERCHENBER

Angaben zu Veröffentlichungen et zur seiben Patentfamilie gehören

1	ıntemati	s Aktenzelchen
	PCT/EP	03/10719

Im Recherchenbericht ngeführtes Patentdokum	ent	Datum der Veröffentlichung		Mitglied(er) der Patentfamille	Datum der Veröffentlichung
WO 0176403	A	18-10-2001	WO 0176403 A1 AU 4224500 A CA 2404653 A1 EP 1280428 A1		18-10-2001 23-10-2001 18-10-2001 05-02-2003
US 6374441	B1	23-04-2002	KEI	NE	
WO 0047155	A	17-08-2000	AU CA EP JP WO US	2992100 A 2362562 A1 1152727 A1 2002536119 T 0047155 A1 2002032927 A1	29-08-2000 17-08-2000 14-11-2001 29-10-2002 17-08-2000 21-03-2002
WO 9725956	Α	24-07-1997	WO EP JP	9725956 A1 0814742 A1 11502146 T	24-07-1997 07-01-1998 23-02-1999

"EXPRESS MAIL" MAILING LABEL
NUMBEREV 331995172 US
DATE OF DEPOSIT May 13, 2005 I HEREBY CERTIFY THAT THIS PAPER OR FEE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE "EXPRESS MAIL POST OFFICE TO ADDRESSEE" SERVICE UNDER 37 CFR 1.10 ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.
Christine Rounds (TYPE) OR PRINTED NAME OF PERSON MAILING PAPER OR FEE) CHICAGO AND COMMANDER OF PERSON MAILING PAPER OR FEE)
(SIGNATURE OF PERSON MAILING PAPER OR FEE)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of)
Manfred Piontek)
on HEADREST FOR A PATIENT-BEARING SURFACE) Examiner: Unknown)
Serial No.: National Stage Entry of Int'l Appln. No.: PCT/EP2003/010719 International Filing Date: 26 Sept. 2003) Art Unit: Unknown)
Filed: Simultaneously herewith) (Docket No. 2619-0038WOUS)

Hartford, Connecticut, May 13, 2005

Mail Stop PCT Commissioner for Patents P.O. BOX 1450 Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

SIR:

Prior to examination on the merits, please amend the above-identified application as follows with reference to the Substitute Specification of the International Application, filed simultaneously herewith:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims begin on page 4 of this paper.

Remarks begin on page 6 of this paper.

Amendments to the Specification:

After the title, please insert the following subheading and paragraph:

CROSS REFERENCE TO RELATED APPLICATIONS

and the second of the second of the second of the first participation of the second of

[0001] Applicants hereby claim foreign priority benefits under 35 U.S.C. § 119 of PCT Patent Application No. PCT/EP2003/010719 filed September 26, 2003 and German Patent Application No. 202 17 825.0 filed November 18, 2002, the disclosures of which are herein incorporated by reference.

Before paragraph [0002], please insert the following subheading: <u>BACKGROUND OF THE INVENTION</u> <u>1. Technical Field</u>

Before paragraph [0003], please insert the following subheading:

2. Background Art

Please insert the following new paragraphs [0005] and [0006] as follows:

[0005] WO 01/76403 A1 shows a headrest including a helmet-like curved rest shell with openings for the eye parts, mouth and nose and a foam material cushion with corresponding openings for the support of the face.

[0006] US 6,374,441 B1 shows a headrest for supporting the face of a patient with the rest having a board on which a foam material cushion is arranged and into which cushion is cut a contour with a hollow space for the eye parts, mouth and nose.

Before paragraph [0008], please insert the following subheading:

SUMMARY OF THE INVENTION

Please amend paragraph [0011] as follows:

[0011] Preferably the headrest is made of a rigid rest shell and a support cushion releasably connectable with the shell. In contrast to customary headrests in the case of which for lateral support of the head the cushion must be made very

thick, that is the head sinks relatively far into the cushion, in the case of the solution according to the invention because of the anatomical shape of the headrest the support cushion can be made thinner. The rest shell is advantageously made of plastic which not only simplifies its manufacture, for example by injection molding methods, but also simplifies the cleaning of the rest shell in daily use of it.

Before paragraph [0015], please insert the following subheading: BRIEF DESCRIPTION OF THE DRAWINGS

Please amend paragraphs [0016] - [0020] as follows:

[0016] Figure $1_{\underline{i}\underline{s}}$ a plan view of the support shell of a first embodiment of the headrest of the invention,

[0017] Figure 2 is a side view of a headrest provided with a support cushion and a fixing belt,

[0018] Figure 3 <u>is a perspective bottom view of a support cushion intended for a support shell according to Figure 1,</u>

[0019] Figure 4 <u>is a partial section through the support shell taken along the line IV-IV in Figure 1, and</u>

[0020] Figure 5 is a plan view corresponding to Figure 1 of a rest shell of a headrest according to a second embodiment of the invention.

Before paragraph [0021], please insert the following subheading:

DETAILED DESCRIPTION OF THE PREFERRED INVENTION

Please add the following new paragraph [0026]:

While the present invention has been illustrated and described with respect to a particular embodiment thereof, it should be appreciated by those of ordinary skill in the art that various modifications to this invention may be made without departing from the spirit and scope of the present invention.

Amendment to the Claims:

Before claim 1, please delete the word "Claims" and substitute the following: What is claimed is:

- 1. (Currently Amended) A headrest for a patient-bearing surface with a rigid support shell and a cushion releasably connectable with the rest shell, characterized by in that the rest shell has an approximately horseshoeshaped form with a central section (14)-for supporting the rear or forehead of a head, which central section has a support surface of approximately spherical shell shape, and with two side sections (16)-spaced from one another, the support surfaces of which side sections conform at least approximately to a common cylindrical surface whose axis runs parallel to a line of symmetry (20)-of the head support running between the side sections (16)- with there being a cheekbone support (18)-on each of the side sections (16)-which cheekbone support projects in the direction toward the other side section (16).
- 2. Cancelled.
- 3. (Currently Amended) The A headrest according to claim 21, further characterized in that wherein the rest shell (10) is made of plastic.
- 4. (Currently Amended) <u>TheA</u> headrest according to claim <u>12 or 3</u>, <u>further characterized in that wherein</u> the support cushion (12) on its side facing the rest shell (10)-carries at least two stick pins (38)-designed for insertion into through going bores (40) in the rest shell-(10).
- 5. (Currently Amended) <u>TheA</u> headrest according to claim 4, further characterized in that wherein the stick pins (36) each have a cylindrical shaft which cylindrical shaft has an elastically resilient band (38) with an external diameter slightly larger than the diameter of said bores.

- 6. (Currently Amended) <u>TheA</u> headrest according to one of claims 1 to 5 <u>claim 1</u>, <u>further characterized in that wherein it</u> is divided into two mirror image similar partial supports (50) along its line of symmetry (20).
- 7. (Currently Amended) The headrest according to one of claims 1 to 6claim 1, further characterized in that wherein the headrest or each partial rest is connected to a fastening block (42) for holding it to a profiled rail.
- 8. (Currently Amended) <u>The A</u> headrest according to <u>one of claims 1 to 7</u> <u>claim 1</u>, <u>further characterized in that wherein on the outer edge of each side section (16) is formed an eye (26) for the fastening of a belt (26) for fixing the head of a patient to the headrest.</u>

Appl. No.: Not Yet Assigne...
Prel. Amdt. dated May 13, 2005

REMARKS

Applicants enclose a Substitute Specification as now amended and a Marked-up Version showing the changes made to the specification.

The above amendments are being presented to include subheadings in the application and to remove multiple dependencies in claims, make formatting corrections and remove reference numerals from its claims in order to place the application in better U.S. form. The claim amendments are made to the originally filed PCT claims.

Should the Examiner have any questions regarding the present application, Applicants respectfully request that the Examiner contact Applicants' representative at the phone number listed below. While Applicants believe no fees are due with the filing of this preliminary amendment, please charge any deficiencies in fees associated with this filing to our Deposit Account No. 13-0235.

Respectfully submitted,

Bv

Marina F. Cunningham Registration No. 38,419 Attorney for Applicants

McCormick, Paulding & Huber LLP CityPlace II 185 Asylum Street Hartford, Connecticut 06103-3402 (860) 549-5290

ENGLISH TRANSLATION OF SPECIFICATION

Translation of International Application No. PCT/EP03/010719 HEADREST FOR A PATIENT-BEARING SURFACE

The invention concerns a headrest for a patient-bearing surface, especially that of an operating table.

A headrest is known from U.S. 6,276,012 B2, which rest consists of a U-shaped part and a plate-shaped section lying between the legs of the U. In the case of a patient lying on his or her back the head of the patient is supported by both of the parts. In the case of the patient lying on his or her stomach the plate-shaped part is swung away so that the head of the patient lies with the forehead on the middle bar of the U, and at least the mouth and nose of the patient lie free. The headrest in its entirety is essentially flat and is cushioned. In the case of the patient lying on his or her back as well as the case of the patient lying on his or her stomach the head is not laterally supported.

From US-A-6,042,184 a lounge chair is known which is provided with a plate-shaped headrest. In the plate-shaped headrest an opening is formed which is surrounded by a circular, not entirely closed, cushion which is fastened to the plate by pressure pins. In this case also, the head of the person can be supported with the person lying on his or her back or with the person lying on his or her stomach, with the face lying free. The headrest is however not well adopted to the shape of human heads and is unsuited to support the head of a patient during an operation where the patient has to be held motionless for a long time and in such a way that the patient is not injured for example by pressure points or the like.

The invention has as its object the provision of a headrest of the previously mentioned kind which allows the head of the patient to be securely held in a desired position both in the case of the patient lying on his or her back and the case of the patient lying on his or her stomach, and for the patient to be supported with comfort.

For solving this object the headrest of the invention has an approximately horseshoe-shape with a central section for supporting the rear of the head or the forehead, the outer support surface of which central section has an approximately spherical shape, and with two side sections spaced from one another, the support surfaces of which side sections approximately conform to a common cylindrical surface whose axis runs parallel to a line of symmetry of the headrest running between the side sections, with a cheekbone support projecting in the direction toward the opposite side section being formed on each of the side sections.

The headrest of the invention is adapted to the particular shape of the human head supports the head on suitable surfaces of the skull, namely the rear of the head or the forehead as well as the cheekbones. By way of the spherical shape and cylindrical curvature of its sections the head is so bedded that it cannot fall to the side. The cheekbone supports on the side sections make possible on one hand a good support of the face in the case of the patient lying on his or her stomach, with however the eye parts and the mouth and nose remaining free for inhaling and exhaling as well as for the use of an anesthesia mask or other aids. Because of the anatomically correct shape of the headrest of the invention the weight of the head is distributed in large area fashion over the sections of the headrest so that localized pressures are avoided and thereby even in the case of lengthy operations pressure points on the head, especially on the face, can be avoided.

Preferably the headrest is made of a rigid rest shell and a support cushion releasably connectable with the shell. In contrast to customary headrests in the case of which for lateral support of the head the cushion must be made very thick, that is the head sinks relatively far into the cushion, in the case of the solution according to the invention because of the anatomical shape of the headrest the support cushion can be made thinner. The rest shell is advantageously

made of plastic which not only simplifies its manufacture, for example by injection molding methods, but also simplifies the cleaning of the rest shell in daily use of it.

Preferably the support cushion on its side facing the rest shell has at least two stick pins designed for insertion into through going bores in the rest shell. This way the support cushion can be quickly and securely connected with the rest shell and can be easily again removed from it. Both these bores and also the stickpins are simply and carefully capable of being cleaned. To avoid an unwanted loosening of the support cushion from the rest shell it can be advantageous if the stick pins on a cylindrical shaft of each have an elastically resilient band whose diameter is slightly larger than the diameter of the bores, so that the stick pins can be pressed into and removed from the bores in the rest shell only with a certain resistance.

The headrest of the invention can be made as one piece or also can be divided into two mirror image similar partial supports. The latter embodiment makes possible a definite suiting of the headrest to different sizes of heads.

For the connecting of the headrest to the patient-bearing surface the headrest or each partial rest can in a known way be connected with a fastening block for holding it to a profiled rail, which rail in turn is fastened to the patient-bearing surface or to a holder connected with the patient-bearing surface. To assure that the patient during an operation does not move his or her head, on the outer edge of each rest side section an eye can be formed for fastening to a belt by means of which the patient's head can be fixed to the headrest.

Further features and advantages of the invention will be apparent from the following description which in combination with the accompanying drawings explain the invention by way of exemplary embodiments. The drawings are:

- Figure 1 a plan view of the support shell of a first embodiment of the headrest of the invention,
- Figure 2 a side view of a headrest provided with a support cushion and a fixing belt,
- Figure 3 a perspective bottom view of a support cushion intended for a support shell according to Figure 1,
- Figure 4 a partial section through the support shell taken along the line IV-IV in Figure 1, and
- Figure 5 a plan view corresponding to Figure 1 of a rest shell of a headrest comprising a second embodiment of the invention.

The headrest illustrated in Figure 1-4 has an approximately horseshoe-shaped form and includes a rest shell, indicated generally at 10, and a support cushion 12 conforming in its shape to that of the shell. The rest shell has a central section 14 designed to support the rear head of a patient (lying on his or her back) or the forehead of a patient (lying on his or her stomach). This central section 14 on its upper or inner side facing the viewer in Figure 1 is of at least nearly spherical shape. Connected to the central section 14 are two side sections 16 which approach one another with their free ends and each of which has a section 18 protruding toward the other side section 16, which sections 18 form a cheekbone support, that is a support which supports in the region of the cheekbones the face of a patient lying on his or her stomach. The side sections 16 conform approximately to a common cylindrical surface whose axis is parallel to the line of symmetry 20 of the headrest and which line of symmetry runs between the two side sections 16. The central opening of the headrest 10 includes a region 22 near the central section 14 which corresponds to the eye parts of the patient's face and a region 24 corresponding to the mouthparts of the patient's face. By the

suiting of the rest shell 14 to the anatomical shape of the head on one hand a better lateral support and on the other hand a support of increased surface area of the head on the headrest is achieved, so that in turn localized pressure loading and therewith the danger of forming pressure points on the head of the patient is avoided.

On the outer edge of each side section 16 is an eye 26 through which a belt 28 can be pulled and by means of which the head of a patient can be fixed to the head support. The belt 28 in doing this is pulled through the eyes 26, following which the ends of the belt are overlapped with one another and are for example fastened by means of a burr type closure, as is indicated in Figure 2. On the inner side of the belt is a pillow 30 through which the belt lies onto the head of the patient.

The support cushion which is connected with the rest shell according to Figure 1 is illustrated in Figure 3. It has a form which suits the shape of the rest shell 10 with a central section 32 and side sections 34. On its side facing the rest shell 10 the support cushion carries stickpins 36 which are formed essentially cylindrically and each of which in a circumferential groove carries an O-ring 38. The stick pins 36 are insertable into bores 40 formed in the rest shell 10 with the measurements of the bores 40 and of the stick pins 36 being so chosen that upon the insertion and withdrawal of the stick pins 36 into or out of the bores 38 a certain opposing resistance is created. The support cushion 12 can however in this way be quickly connected to or removed from the rest shell 10 so that the rest shell 10 and the support cushion 12 can be easily cleaned hygienically and without problem.

Figure 4 shows a fastening block 42 connected with the rest shell which block has a cross-sectionally shaped opening 44 which is slidable onto a shaped rail and is fixed to the rest shell 10 by a screw 46. By means of a clamping screw 48 the block 42 and thereby the entire headrest can be fixed to the shaped rail.

Figure 5 shows a two-part rest shell for a two-part headrest. The two partial shells 50 are formed mirror image symmetrical to one another with respect to the line of symmetry 20 and correspond in all details to the corresponding sections of the one piece rest shell of Figure 1 with the exception that each partial shell 50 is provided with a fastening block 42. The associated support cushion is divided similarly to the rest shell, as this is indicated in Figure 3 by the broken lines 52. The embodiment according to Figure 5 offers the possibility of changing the spacing between the two partial rests of the headrest to suit the size of the head to be supported.

Claims

- 1. A headrest for a patient-bearing surface, characterized by an approximately horseshoe-shaped form with a central section (14) for supporting the rear or forehead of a head, which central section has a support surface of approximately spherical shape, and with two side sections (16) spaced from one another, the support surfaces of which side sections conform at least approximately to a common cylindrical surface whose axis runs parallel a line of symmetry (20) running between the side sections (16) of the head support, with there being a cheekbone support (18) on each of the side sections (16) which cheekbone support projects in the direction toward the other side section (16).
- 2. A headrest according to claim 1, further characterized in that it includes a rigid rest shell (10) and a support cushion (12) releasably connected with the rest shell.
- 3. A headrest according to claim 2, further characterized in that the rest shell (10) is made of plastic.
- 4. A headrest according to claim 2 or 3, further characterized in that the support cushion (12) on its side facing the rest shell (10) carries at least two stick pins (38) designed for insertion into through going bores (40) in the rest shell (10).
- 5. A headrest according to claim 4, further characterized in that the stick pins (36) each have a cylindrical shaft which cylindrical shaft has an elastically resilient band (38) with an external diameter slightly larger than the diameter of said bores.

- 6. A headrest according to one of claims 1 to 5, further characterized in that it is divided into two mirror image similar partial supports (50) along its line of symmetry (20).
- A headrest according to one of claims 1 to 6, further characterized in that the headrest or each partial rest is connected to a fastening block (42) for holding it to a profiled rail.
- 8. A headrest according to one of claims 1 to 7, further characterized in that on the outer edge of each side section (16) is formed an eye (26) for the fastening of a belt (26) for fixing the head of a patient to the headrest.

Abstract

A headrest for a patient-bearing surface, having an approximately horseshoe-shaped form and comprising a central section (14) for supporting the back of the head or the forehead, the bearing surface thereof being at least approximately spherical shell-shaped, also comprising two side sections (16) which are arranged at a distance from each other and whose bearing surfaces conform at least approximately to a common cylindrical surface whose axis is parallel to a symmetrical line (20) of the headrest extending between the side surfaces (16). A cheekbone support (18), which protrudes in the direction of the other side section (16), is provided on each side section (16).

MARKED-UP VERSION SHOWING CHANGES

HEADREST FOR A PATIENT-BEARING SURFACE

Applicants hereby claim foreign priority benefits under 35 U.S.C. § 119 of PCT Patent Application No. PCT/EP2003/010719 filed September 26, 2003 and German Patent Application No. 202 17 825.0 filed November 18, 2002, the disclosures of which are herein incorporated by reference.

BACKGROUND OF THE INVENTION

Technical Field

[0002] The invention concerns a headrest for a patient-bearing surface, especially that of an operating table.

Background Art

[0003] A headrest is known from U.S. 6,276,012 B2, which rest consists of a U-shaped part and a plate-shaped section lying between the legs of the U. In the case of a patient lying on his or her back the head of the patient is supported by both of the parts. In the case of the patient lying on his or her stomach the plate-shaped part is swung away so that the head of the patient lies with the forehead on the middle bar of the U, and at least the mouth and nose of the patient lie free. The headrest in its entirety is essentially flat and is cushioned. In the case of the patient lying on his or her back as well as the case of the patient lying on his or her stomach the head is not laterally supported.

[0004] From US-A-6,042,184 a lounge chair is known which is provided with a plate-shaped headrest. In the plate-shaped headrest an opening is formed which is surrounded by a circular, not entirely closed, cushion which is fastened to the plate by push buttons. In this case also, the head of the person can be supported with the person lying on his or her back or with the person lying on his or her stomach, with the face lying free. The headrest is however not well adopted to the shape of human heads and is unsuited to support the head of a patient during an operation where the patient has to be held motionless for a long time and in such a way that the patient is not injured for example by pressure points or the like.

[0005] WO 01/76403 A1 shows a headrest including a helmet-like curved rest shell with openings for the eye parts, mouth and nose and a foam material cushion with corresponding openings for the support of the face.

[0006] US 6,374,441 B1 shows a headrest for supporting the face of a patient with the rest having a board on which a foam material cushion is arranged and into which cushion is cut a contour with a hollow space for the eye parts, mouth and nose.

[0007] The invention has as its object the provision of a headrest of the previously mentioned kind which allows the head of the patient to be securely held in a desired position both in the case of the patient lying on his or her back and the case of the patient lying on his or her stomach, and for the patient to be supported with comfort.

SUMMARY OF THE INVENTION

[0008] The invention has as its object the provision of a headrest of the previously mentioned kind which allows the head of the patient to be securely held in a desired position both in the case of the patient lying on his or her back and the case of the patient lying on his or her stomach, and for the patient to be supported with comfort.

[0009] For solving this object the headrest of the invention has an approximately horseshoe-shape with a central section for supporting the rear of the head or the forehead, the support surface of which central section has an approximately spherical shell shape, and with two side sections spaced from one another, the support surfaces of which side sections approximately conform to a common cylindrical surface whose axis runs parallel to a line of symmetry of the headrest running between the side sections, with a cheekbone support projecting in the direction toward the opposite side section being formed on each of the side sections.

[0010] The headrest of the invention is adapted to the particular shape of the human head and supports the head on suitable surfaces of the skull, namely the rear of the head or the forehead as well as the cheekbones. By way of the spherical shell shape and cylindrical curvature respectively of its sections the head is so bedded that it cannot fall to the side. The cheekbone supports on the side sections make possible on one hand a good support of the face in the case of the patient lying on his or her stomach, with however the eye parts and the mouth and nose remaining free for inhaling and exhaling as well as for the use of an anesthesia mask or other aids. Because of the anatomically correct shape of the headrest of the invention the weight of the head is distributed in large area fashion over the sections of the headrest so that localized pressures are reduced and thereby even in the case of lengthy operations pressure points on the head, especially on the face, can be avoided.

[0011] Preferably the headrest is made of a rigid rest shell and a support cushion releasably connectable with the shell. In contrast to customary headrests in the case of which for lateral support of the head the cushion must be made very thick, that is the head sinks relatively far into the cushion, in the case of the solution according to the invention because of the anatomical shape of the headrest the support cushion can be made thinner. The rest shell is advantageously made of plastic which not only simplifies its manufacture, for example by injection molding methods, but also simplifies the cleaning of the rest shell in daily use of it.

[0012] Preferably the support cushion on its side facing the rest shell has at least two stick pins designed for insertion into through going bores in the rest shell. This way the support cushion can be quickly and securely connected with the rest shell and can be easily again removed from it. Both these bores and also the stickpins can be cleaned simply and without a problem. To avoid an unwanted loosening of the support cushion from the rest shell it can be advantageous if the stick pins on a cylindrical shaft each have an elastically resilient band whose diameter is slightly larger than the diameter of the bores, so

that the stick pins can be pressed into and removed from the bores in the rest shell only with a certain resistance.

[0013] The headrest of the invention can be made as one piece or also can be divided into two mirror image similar partial supports along their line of symmetry. The latter embodiment makes possible a definite suiting of the headrest to different sizes of heads.

[0014] For the connecting of the headrest to the patient-bearing surface the headrest or each partial rest can in a known way be connected with a fastening block for holding it to a profiled rail, which rail in turn is fastened to the patient-bearing surface or to a holder connected with the patient-bearing surface. To assure that the patient during an operation does not move his or her head, on the outer edge of each side section an eye can be formed for fastening a belt by means of which the patient's head can be fixed to the headrest.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] Further features and advantages of the invention will be apparent from the following description which in combination with the accompanying drawings explain the invention by way of exemplary embodiments. The drawings are:

[0016] Figure 1 is a plan view of the support shell of a first embodiment of the headrest of the invention,

[0017] Figure 2 is a side view of a headrest provided with a support cushion and a fixing belt,

[0018] Figure 3 is a perspective bottom view of a support cushion intended for a support shell according to Figure 1,

[0019] Figure 4 is a partial section through the support shell taken along the line IV-IV in Figure 1, and

Marked-Up Version Showing Changes Made

[0020] Figure 5 is a plan view corresponding to Figure 1 of a rest shell of a headrest according to a second embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

The headrest illustrated in Figures 1-4 has an approximately [0021] horseshoe-shaped form and includes a rest shell, indicated generally at 10, and a support cushion 12 conforming in its shape to that of the shell. The rest shell has a central section 14 designed to support the rear head of a patient (lying on his or her back) or the forehead of a patient (lying on his or her stomach). This central section 14 on its upper or inner side facing the viewer in Figure 1 is of at least nearly spherical shell shape. Connected to the central section 14 are two side sections 16 which approach one another with their free ends and each of which has a section 18 protruding toward the other side section 16, which sections 18 form a cheekbone support, that is a support which supports in the region of the cheekbones the face of a patient lying on his or her stomach. The side sections 16 conform approximately to a common cylindrical surface whose axis is parallel to the line of symmetry 20 of the headrest and which line of symmetry runs between the two side sections 16. The central opening of the headrest 10 includes a region 22 near the central section 14 which corresponds to the eye parts of the patient's face and a region 24 corresponding to the mouthparts of the patient's face. By the suiting of the rest shell 14 to the anatomical shape of the head on one hand a better lateral support and on the other hand a support of increased surface area of the head on the headrest is achieved, so that in turn localized pressure loading and therewith the risk of forming pressure points on the head of the patient is reduced.

[0022] On the outer edge of each side section 16 is an eye 26 through which a belt 28 can be pulled by means of which the head of a patient can be fixed to the head support. The belt 28 in doing this is pulled through the eyes 26, following which the ends of the belt are overlapped with one another and are for example fastened by means of a Velcro fastener, as is indicated in Figure 2. On

the inner side of the belt is a pillow 30 through which the belt lies onto the head of the patient.

[0023] The support cushion which is connected with the rest shell according to Figure 1 is illustrated in Figure 3. It has a form which suits the shape of the rest shell 10 with a central section 32 and side sections 34. On its side facing the rest shell 10 the support cushion carries stickpins 36 which are formed essentially cylindrically and each of which in a circumferential groove carries an O-ring 38. The stick pins 36 are insertable into bores 40 formed in the rest shell 10 with the measurements of the bores 40 and of the stick pins 36 being so chosen that upon the insertion and withdrawal of the stick pins 36 into or out of the bores 40 a certain opposing resistance is created. The support cushion 12 can however in this way be quickly connected to or removed from the rest shell 10 so that the rest shell 10 and the support cushion 12 can be easily cleaned hygienically and without problem.

[0024] Figure 4 shows a fastening block 42 connected with the rest shell which block has a profiled opening 44 which is slidable onto a shaped rail and is fixed to the rest shell 10 by a screw 46. By means of a clamping screw 48 the block 42 and thereby the entire headrest can be fixed to the shaped rail.

[0025] Figure 5 shows a two-part rest shell for a two-part headrest. The two partial shells 50 are formed mirror image symmetrical to one another with respect to the line of symmetry 20 and correspond in all details to the corresponding sections of the one piece rest shell of Figure 1 with the exception that each partial shell 50 is provided with a fastening block 42. The associated support cushion is divided similarly to the rest shell, as this is indicated in Figure 3 by the broken lines 52. The embodiment according to Figure 5 offers the possibility of changing the spacing between the two partial rests of the headrest to suit the size of the head to be supported.

[0026] While the present invention has been illustrated and described with respect to a particular embodiment thereof, it should be appreciated by those of

ordinary skill in the art that various modifications to this invention may be made without departing from the spirit and scope of the present invention.

Claims

What is Claimed is:

- 1. A headrest for a patient-bearing surface, characterized by an approximately horseshoe-shaped form with a central section (14) for supporting the rear or forehead of a head, which central section has a support surface of approximately spherical shape, and with two side sections (16) spaced from one another, the support surfaces of which side sections conform at least approximately to a common cylindrical surface whose axis runs parallel a line of symmetry (20) running between the side sections (16) of the head support, with there being a cheekbone support (18) on each of the side sections (16) which cheekbone support projects in the direction toward the other side section (16).
- 2. A headrest according to claim 1, further characterized in that it includes a rigid rest shell (10) and a support cushion (12) releasably connected with the rest shell.
- 3. A headrest according to claim 2, further characterized in that the rest shell (10) is made of plastic.
- 4. A headrest according to claim 2 or 3, further characterized in that the support cushion (12) on its side facing the rest shell (10) carries at least two stick pins (38) designed for insertion into through going bores (40) in the rest shell (10).
- 5. A headrest according to claim 4, further characterized in that the stick pins (36) each have a cylindrical shaft which cylindrical shaft has an elastically resilient band (38) with an external diameter slightly larger than the diameter of said bores.

- 6. A headrest according to one of claims 1 to 5, further characterized in that it is divided into two mirror image similar partial supports (50) along its line of symmetry (20).
- 7. A headrest according to one of claims 1 to 6, further characterized in that the headrest or each partial rest is connected to a fastening block (42) for holding it to a profiled rail.
- 8. A headrest according to one of claims 1 to 7, further characterized in that on the outer edge of each side section (16) is formed an eye (26) for the fastening of a belt (26) for fixing the head of a patient to the headrest.

Abstract

A headrest for a patient-bearing surface, having an approximately horseshoe-shaped form and comprising a central section (14) for supporting the back of the head or the forehead, the bearing surface thereof being at least approximately spherical shell-shaped, also comprising two side sections (16) which are arranged at a distance from each other and whose bearing surfaces conform at least approximately to a common cylindrical surface whose axis is parallel to a symmetrical line (20) of the headrest extending between the side surfaces (16). A cheekbone support (18), which protrudes in the direction of the other side section (16), is provided on each side section (16).

SUBSTITUTE SPECIFICATION

HEADREST FOR A PATIENT-BEARING SURFACE

Applicants hereby claim foreign priority benefits under 35 U.S.C. §

119 of PCT Patent Application No. PCT/EP2003/010719 filed September 26, 2003

and German Patent Application No. 202 17 825.0 filed November 18, 2002, the

disclosures of which are herein incorporated by reference.

BACKGROUND OF THE INVENTION

Technical Field

[0002] The invention concerns a headrest for a patient-bearing surface, especially that of an operating table.

2. Background Art

[0003] A headrest is known from U.S. 6,276,012 B2, which rest consists of a U-shaped part and a plate-shaped section lying between the legs of the U. In the case of a patient lying on his or her back the head of the patient is supported by both of the parts. In the case of the patient lying on his or her stomach the plate-shaped part is swung away so that the head of the patient lies with the forehead on the middle bar of the U, and at least the mouth and nose of the patient lie free. The headrest in its entirety is essentially flat and is cushioned. In the case of the patient lying on his or her stomach the head is not laterally supported.

[0004] From US-A-6,042,184 a lounge chair is known which is provided with a plate-shaped headrest. In the plate-shaped headrest an opening is formed which is surrounded by a circular, not entirely closed, cushion which is fastened to the plate by push buttons. In this case also, the head of the person can be supported with the person lying on his or her back or with the person lying on his or her stomach, with the face lying free. The headrest is however not well adopted to the shape of human heads and is unsuited to support the head of a patient during an operation where the patient has to be held motionless for a long time and in such a way that the patient is not injured for example by pressure points or the like.

[0005] WO 01/76403 A1 shows a headrest including a helmet-like curved rest shell with openings for the eye parts, mouth and nose and a foam material cushion with corresponding openings for the support of the face.

[0006] US 6,374,441 B1 shows a headrest for supporting the face of a patient with the rest having a board on which a foam material cushion is arranged and into which cushion is cut a contour with a hollow space for the eye parts, mouth and nose.

[0007] The invention has as its object the provision of a headrest of the previously mentioned kind which allows the head of the patient to be securely held in a desired position both in the case of the patient lying on his or her back and the case of the patient lying on his or her stomach, and for the patient to be supported with comfort.

SUMMARY OF THE INVENTION

[0008] The invention has as its object the provision of a headrest of the previously mentioned kind which allows the head of the patient to be securely held in a desired position both in the case of the patient lying on his or her back and the case of the patient lying on his or her stomach, and for the patient to be supported with comfort.

[0009] For solving this object the headrest of the invention has an approximately horseshoe-shape with a central section for supporting the rear of the head or the forehead, the support surface of which central section has an approximately spherical shell shape, and with two side sections spaced from one another, the support surfaces of which side sections approximately conform to a common cylindrical surface whose axis runs parallel to a line of symmetry of the headrest running between the side sections, with a cheekbone support projecting in the direction toward the opposite side section being formed on each of the side sections.

[0010] The headrest of the invention is adapted to the particular shape of the human head and supports the head on suitable surfaces of the skull, namely the rear of the head or the forehead as well as the cheekbones. By way of the spherical shell shape and cylindrical curvature respectively of its sections the head is so bedded that it cannot fall to the side. The cheekbone supports on the side sections make possible on one hand a good support of the face in the case of the patient lying on his or her stomach, with however the eye parts and the mouth and nose remaining free for inhaling and exhaling as well as for the use of an anesthesia mask or other aids. Because of the anatomically correct shape of the headrest of the invention the weight of the head is distributed in large area fashion over the sections of the headrest so that localized pressures are reduced and thereby even in the case of lengthy operations pressure points on the head, especially on the face, can be avoided.

[0011] In contrast to customary headrests in the case of which for lateral support of the head the cushion must be made very thick, that is the head sinks relatively far into the cushion, in the case of the solution according to the invention because of the anatomical shape of the headrest the support cushion can be made thinner. The rest shell is advantageously made of plastic which not only simplifies its manufacture, for example by injection molding methods, but also simplifies the cleaning of the rest shell in daily use of it.

[0012] Preferably the support cushion on its side facing the rest shell has at least two stick pins designed for insertion into through going bores in the rest shell. This way the support cushion can be quickly and securely connected with the rest shell and can be easily again removed from it. Both these bores and also the stickpins can be cleaned simply and without a problem. To avoid an unwanted loosening of the support cushion from the rest shell it can be advantageous if the stick pins on a cylindrical shaft each have an elastically resilient band whose diameter is slightly larger than the diameter of the bores, so that the stick pins can be pressed into and removed from the bores in the rest shell only with a certain resistance.

[0013] The headrest of the invention can be made as one piece or also can be divided into two mirror image similar partial supports along their line of symmetry. The latter embodiment makes possible a definite suiting of the headrest to different sizes of heads.

For the connecting of the headrest to the patient-bearing surface the headrest or each partial rest can in a known way be connected with a fastening block for holding it to a profiled rail, which rail in turn is fastened to the patient-bearing surface or to a holder connected with the patient-bearing surface. To assure that the patient during an operation does not move his or her head, on the outer edge of each side section an eye can be formed for fastening a belt by means of which the patient's head can be fixed to the headrest.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] Further features and advantages of the invention will be apparent from the following description which in combination with the accompanying drawings explain the invention by way of exemplary embodiments. The drawings are:

[0016] Figure 1 is a plan view of the support shell of a first embodiment of the headrest of the invention.

[0017] Figure 2 is a side view of a headrest provided with a support cushion and a fixing belt,

[0018] Figure 3 is a perspective bottom view of a support cushion intended for a support shell according to Figure 1,

[0019] Figure 4 is a partial section through the support shell taken along the line IV-IV in Figure 1, and

[0020] Figure 5 is a plan view corresponding to Figure 1 of a rest shell of a headrest according to a second embodiment of the invention.

Substitute Specification

<u>DETAILED DESCRIPTION OF THE INVENTION</u>

[0021] The headrest illustrated in Figures 1-4 has an approximately horseshoe-shaped form and includes a rest shell, indicated generally at 10, and a support cushion 12 conforming in its shape to that of the shell. The rest shell has a central section 14 designed to support the rear head of a patient (lying on his or her back) or the forehead of a patient (lying on his or her stomach). This central section 14 on its upper or inner side facing the viewer in Figure 1 is of at least nearly spherical shell shape. Connected to the central section 14 are two side sections 16 which approach one another with their free ends and each of which has a section 18 protruding toward the other side section 16, which sections 18 form a cheekbone support, that is a support which supports in the region of the cheekbones the face of a patient lying on his or her stomach. The side sections 16 conform approximately to a common cylindrical surface whose axis is parallel to the line of symmetry 20 of the headrest and which line of symmetry runs between the two side sections 16. The central opening of the headrest 10 includes a region 22 near the central section 14 which corresponds to the eye parts of the patient's face and a region 24 corresponding to the mouthparts of the patient's face. By the suiting of the rest shell 14 to the anatomical shape of the head on one hand a better lateral support and on the other hand a support of increased surface area of the head on the headrest is achieved, so that in turn localized pressure loading and therewith the risk of forming pressure points on the head of the patient is reduced.

On the outer edge of each side section 16 is an eye 26 through which a belt 28 can be pulled by means of which the head of a patient can be fixed to the head support. The belt 28 in doing this is pulled through the eyes 26, following which the ends of the belt are overlapped with one another and are for example fastened by means of a Velcro fastener, as is indicated in Figure 2. On the inner side of the belt is a pillow 30 through which the belt lies onto the head of the patient.

[0023] The support cushion which is connected with the rest shell according to Figure 1 is illustrated in Figure 3. It has a form which suits the shape of the rest shell 10 with a central section 32 and side sections 34. On its side facing the rest shell 10 the support cushion carries stickpins 36 which are formed essentially cylindrically and each of which in a circumferential groove carries an O-ring 38. The stick pins 36 are insertable into bores 40 formed in the rest shell 10 with the measurements of the bores 40 and of the stick pins 36 being so chosen that upon the insertion and withdrawal of the stick pins 36 into or out of the bores 40 a certain opposing resistance is created. The support cushion 12 can however in this way be quickly connected to or removed from the rest shell 10 so that the rest shell 10 and the support cushion 12 can be easily cleaned hygienically and without problem.

[0024] Figure 4 shows a fastening block 42 connected with the rest shell which block has a profiled opening 44 which is slidable onto a shaped rail and is fixed to the rest shell 10 by a screw 46. By means of a clamping screw 48 the block 42 and thereby the entire headrest can be fixed to the shaped rail.

[0025] Figure 5 shows a two-part rest shell for a two-part headrest. The two partial shells 50 are formed mirror image symmetrical to one another with respect to the line of symmetry 20 and correspond in all details to the corresponding sections of the one piece rest shell of Figure 1 with the exception that each partial shell 50 is provided with a fastening block 42. The associated support cushion is divided similarly to the rest shell, as this is indicated in Figure 3 by the broken lines 52. The embodiment according to Figure 5 offers the possibility of changing the spacing between the two partial rests of the headrest to suit the size of the head to be supported.

[0026] While the present invention has been illustrated and described with respect to a particular embodiment thereof, it should be appreciated by those of ordinary skill in the art that various modifications to this invention may be made without departing from the spirit and scope of the present invention.

[0023] The support cushion which is connected with the rest shell according to Figure 1 is illustrated in Figure 3. It has a form which suits the shape of the rest shell 10 with a central section 32 and side sections 34. On its side facing the rest shell 10 the support cushion carries stickpins 36 which are formed essentially cylindrically and each of which in a circumferential groove carries an O-ring 38. The stick pins 36 are insertable into bores 40 formed in the rest shell 10 with the measurements of the bores 40 and of the stick pins 36 being so chosen that upon the insertion and withdrawal of the stick pins 36 into or out of the bores 40 a certain opposing resistance is created. The support cushion 12 can however in this way be quickly connected to or removed from the rest shell 10 so that the rest shell 10 and the support cushion 12 can be easily cleaned hygienically and without problem.

[0024] Figure 4 shows a fastening block 42 connected with the rest shell which block has a profiled opening 44 which is slidable onto a shaped rail and is fixed to the rest shell 10 by a screw 46. By means of a clamping screw 48 the block 42 and thereby the entire headrest can be fixed to the shaped rail.

[0025] Figure 5 shows a two-part rest shell for a two-part headrest. The two partial shells 50 are formed mirror image symmetrical to one another with respect to the line of symmetry 20 and correspond in all details to the corresponding sections of the one piece rest shell of Figure 1 with the exception that each partial shell 50 is provided with a fastening block 42. The associated support cushion is divided similarly to the rest shell, as this is indicated in Figure 3 by the broken lines 52. The embodiment according to Figure 5 offers the possibility of changing the spacing between the two partial rests of the headrest to suit the size of the head to be supported.

[0026] While the present invention has been illustrated and described with respect to a particular embodiment thereof, it should be appreciated by those of ordinary skill in the art that various modifications to this invention may be made without departing from the spirit and scope of the present invention.

What is Claimed is:

- 1. A headrest for a patient-bearing surface, characterized by an approximately horseshoe-shaped form with a central section (14) for supporting the rear or forehead of a head, which central section has a support surface of approximately spherical shape, and with two side sections (16) spaced from one another, the support surfaces of which side sections conform at least approximately to a common cylindrical surface whose axis runs parallel a line of symmetry (20) running between the side sections (16) of the head support, with there being a cheekbone support (18) on each of the side sections (16) which cheekbone support projects in the direction toward the other side section (16).
- 2. A headrest according to claim 1, further characterized in that it includes a rigid rest shell (10) and a support cushion (12) releasably connected with the rest shell.
- 3. A headrest according to claim 2, further characterized in that the rest shell (10) is made of plastic.
- 4. A headrest according to claim 2 or 3, further characterized in that the support cushion (12) on its side facing the rest shell (10) carries at least two stick pins (38) designed for insertion into through going bores (40) in the rest shell (10).
- 5. A headrest according to claim 4, further characterized in that the stick pins (36) each have a cylindrical shaft which cylindrical shaft has an elastically resilient band (38) with an external diameter slightly larger than the diameter of said bores.

- 6. A headrest according to one of claims 1 to 5, further characterized in that it is divided into two mirror image similar partial supports (50) along its line of symmetry (20).
- A headrest according to one of claims 1 to 6, further characterized in that the headrest or each partial rest is connected to a fastening block (42) for holding it to a profiled rail.
- 8. A headrest according to one of claims 1 to 7, further characterized in that on the outer edge of each side section (16) is formed an eye (26) for the fastening of a belt (26) for fixing the head of a patient to the headrest.

Abstract

A headrest for a patient-bearing surface, having an approximately horseshoe-shaped form and comprising a central section (14) for supporting the back of the head or the forehead, the bearing surface thereof being at least approximately spherical shell-shaped, also comprising two side sections (16) which are arranged at a distance from each other and whose bearing surfaces conform at least approximately to a common cylindrical surface whose axis is parallel to a symmetrical line (20) of the headrest extending between the side surfaces (16). A cheekbone support (18), which protrudes in the direction of the other side section (16), is provided on each side section (16).

ENGLISH TRANSLATION OF CHANGED CLAIMS

Changed Claims

- 1. A headrest for a patient-bearing surface with a rigid support shell (10) and a cushion (12) releasably connectable with the rest shell, characterized in that the rest shell (10) has an approximately horseshoe-shaped form with a central section (14) for supporting the rear or forehead of a head, which central section has a support surface of approximately spherical shell shape, and with two side sections (16) spaced from one another, the support surfaces of which side sections conform at least approximately to a common cylindrical surface whose axis runs parallel to a line of symmetry (20) of the head support running between the side sections (16), with there being a cheekbone support (18) on each of the side sections (16) which cheekbone support projects in the direction toward the other side section (16).
- 2. A headrest according to claim 1, further characterized in that the rest shell (10) is made of plastic.
- 3. A headrest according to claim 1 or 2, further characterized in that the support cushion (12) on its side facing the rest shell (10) carries at least two stick pins (38) designed for insertion into through going bores (40) in the rest shell (10).
- 4. A headrest according to claim 3, further characterized in that the stick pins (36) each have a cylindrical shaft which cylindrical shaft has an elastically resilient band (38) with an external diameter slightly larger than the diameter of said bores.
- 5. A headrest according to one of claims 1 to 4, further characterized in that it is divided into two mirror image similar partial supports (50) along its line of symmetry (20).

- 6. A headrest according to one of claims 1 to 5, further characterized in that the headrest or each partial rest is connected to a fastening block (42) for holding it to a profiled rail.
- 7. A headrest according to one of claims 1 to 6, further characterized in that on the outer edge of each side section (16) is formed an eye (26) for the fastening of a belt for fixing the head of a patient to the headrest.

ENGLISH TRANSLATION OF CHANGED PAGES

Changed Pages HEADREST FOR A PATIENT-BEARING SURFACE

The invention concerns a headrest for a patient-bearing surface, especially that of an operating table, according to the preamble of claim 1.

A headrest is known from U.S. 6,276,012 B2, which rest consists of a U-shaped part and a plate-shaped section lying between the legs of the U. In the case of a patient lying on his or her back the head of the patient is supported by both of the parts. In the case of the patient lying on his or her stomach the plate-shaped part is swung away so that the head of the patient lies with the forehead on the middle bar of the U, and at least the mouth and nose of the patient lie free. The headrest in its entirety is essentially flat and is cushioned. In the case of the patient lying on his or her back as well as the case of the patient lying on his or her stomach the head is laterally supported.

From US-A-6,042,184 a lounge chair is known which is provided with a plate-shaped headrest. In the plate-shaped headrest an opening is formed which is surrounded by a circular, not entirely closed, cushion which is fastened to the plate as by push buttons. In this case also the head of the person can be supported with the person lying on his or her back or with the person lying on his or her stomach, with the face lying free. The headrest is however not well adopted to the shape of human heads and is unsuited to support the head of a patient during an operation where the patient has to be held motionless for a long time and in such a way that the patient is not injured for example by pressure points or the like.

WO 01/76403 A1 shows a headrest including a helmet-like curved rest shell with openings for the eye parts, mouth and nose and a foam material cushion with corresponding openings for the support of the face.

US 6,374,441 B1 shows a headrest for supporting the face of a patient with the rest having a board on which a foam material cushion is arranged and into which cushion is cut a contour with a hollow space for the eye parts, mouth and nose.

The invention has as its object the provision of a headrest of the previously mentioned kind which allows the head of the patient to be securely held in a desired position both in the case of the patient lying on his or her back and the case of the patient lying on his or her stomach, and for the patient to be supported with comfort.

For solving this object the headrest of the invention has an approximately horseshoe-shape with a central section for supporting the rear of the head or the forehead, the outer support surface of which central section has an approximately spherical shell shape, and with two side sections spaced from one another, the support surfaces of which side sections approximately conform to a common cylindrical surface whose axis runs parallel to a line of symmetry of the headrest running between the side sections, with a cheekbone support projecting in the direction toward the opposite side section being formed on each of the side sections.

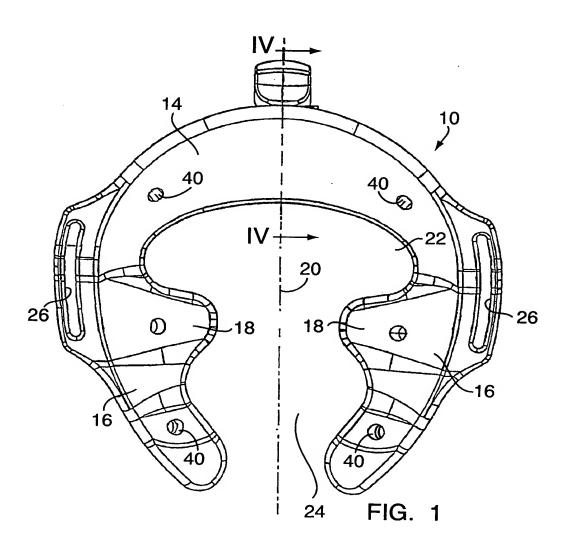
The headrest of the invention is adapted to the particular shape of the human head and supports the head on suitable surfaces of the skull, namely the rear of the head or the forehead as well as the cheekbones. By way of the spherical shell shape and cylindrical curvature of its sections the head is so bedded that it cannot fall to the side. The cheekbone supports on the side sections make possible on one hand a good support of the face in the case of the patient lying on his or her stomach, with however the eye parts and the mouth and nose remaining free for inhaling and exhaling as well as for the use of an anesthesia mask or other aids. Because of the anatomically correct shape of the headrest of the invention the weight of the head is distributed in large area fashion over the sections of the headrest so that localized pressures are reduced and thereby even in the case of lengthy operations pressure points on the head, especially on the face, can be avoided.

In contrast to customary headrests in the case of which for lateral support of the head the cushion must be made very thick, that is the head sinks relatively far into the cushion, in the case of the solution according to the invention because of the anatomical shape of the headrest the support cushion can be made thinner. The rest shell is advantageously

McCormick, Paulding & Huber LLP
Fitte: HEADREST FOR A PATIENT-BEARING SURFACE
First Named Inventor: Manfred Piontek
Serial Number: Not yet known
Attorney Docket Number: 2619-0038WOUS

FILE COPY ---

1/2



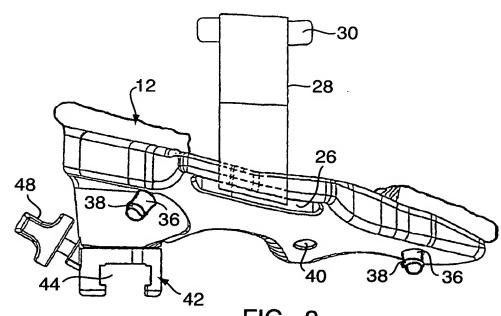
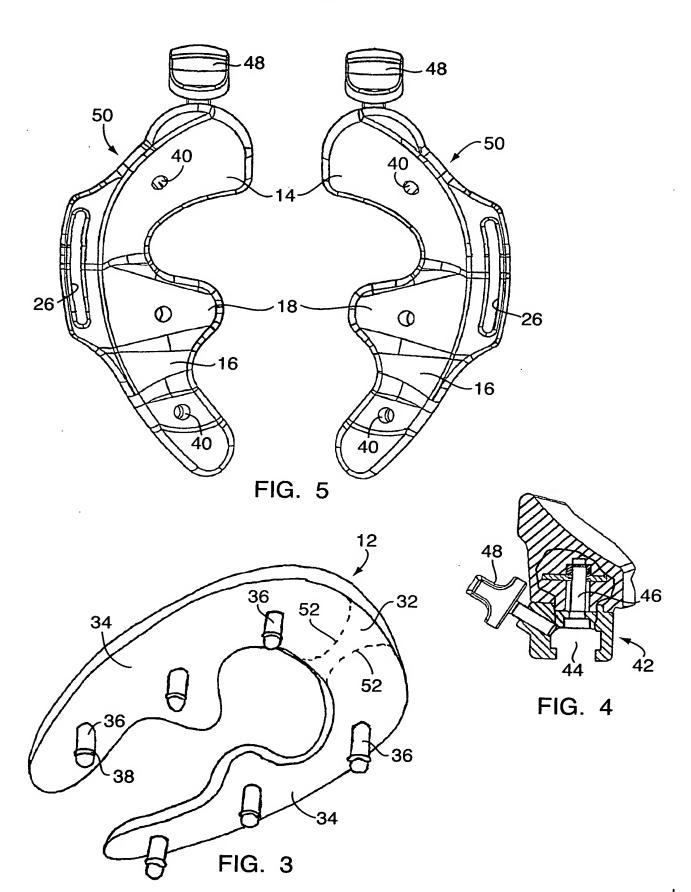


FIG. 2

McCormick, Paulding & Huber LLP
Title: HEADREST FOR A PATIENT-BEARING SURFACE
First Named Inventor: Manfred Piontek
Serial Number: Not yet known
Attorney Docket Number: 2619-0038WOUS

CONTROL OF THE

2/2



「から、ここと、「理論」が、現場の集中で、よる

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of)
Manfred Piontek)
on HEADREST FOR A PATIENT-BEARING SURFACE) Examiner: Unknown))
Serial No.: 'National Stage Entry of Int'l Appln. No. : PCT/EP2003/010719 International Filing Date: 26 Sept. 2003)) Art Unit: Unknown))
Filed: Simultaneously herewith)) (Docket No. 2619-0038WOUS)

Hartford, Connecticut, May 13, 2005

Mail Stop PCT Commissioner for Patents P.O. BOX 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

SIR:

Attached hereto is Form PTO-1449 listing documents believed relevant to the subject application. It is respectfully requested that the Examiner consider these documents and an initialed copy of the form be returned to the undersigned.

This disclosure statement should not be construed as a representation that a search has been made or that no other material information as defined in 37 C.F.R. § 1.56 (a) exists. In addition, the cited documents are not necessarily analogous art.

It is believed that this disclosure complies with the requirements of 37 C.F.R. § 1.56, 1.97, and 1.98 and the Manual of Patent Examining Procedures § 609. If for some reason, the Examiner considers otherwise, it is respectfully requested that the Applicants' representative be called so that any deficiencies can be remedied.

Since no action on the merits has issued in this application, Applicants believe no fee is due for filing this Information Disclosure Statement. If it is determined that a fee is required, please charge deposit account no. 13-0235.

Respectfully submitted,

and the first of the second of

By 🖊

Marina F. Cunningham Registration No. 38,419 Attorney for Applicants

McCormick, Paulding & Huber LLP CityPlace II 185 Asylum Street Hartford, Connecticut 06103-3402 (860) 549-5290

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT BY APPLICANT(S)

Docket No.: 2619-0038WOUS

Applicant: Manfred Piontek
Title: Headrest for a Patient-Bearing

U.S. Serial No.: Unknown
U.S. Filing Date: Herewith
Group Art Unit: Unknown

Surface

U.S. PATENT DOCUMENTS

Examiner's	Patent	Patent	<u>Name</u>	Class	
<u>Initials</u>	Number	<u>Date</u>		<u>Subclass</u>	
	6,042,184	03/28/2000	Kofoed	297/391	
	6,276,012 B2	08/21/2001	Borders	5/622	
	6,374,441 B1	04/23/2002	Begell	5/638	
FOREIGN PATENT DOCUMENTS					

Examiner's <u>Initials</u>	Document <u>Number</u>	<u>Date</u>	Country	Trans <u>Yes</u>	slation <u>No</u>
	WO 01/76403 A1	10/18/2001	PCT	X	

OTHER DOCUMENTS

Examiner's <u>Initials</u>	
EXAMINER	DATE CONSIDERED

EXAMINER:

Initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization International Bureau



1881 - 1880 - 1880 - 1880 - 1880 - 1880 - 1880 - 1880 - 1880 - 1880 - 1880 - 1880 - 1880 - 1880 - 1880 - 1880

(43) International Publication Date 18 October 2001 (18.10.2001)

PCT

(10) International Publication Number WO 01/76403 A1

(51) International Patent Classification7: A47C 20/00 A42B 3/00,

(21) International Application Number: PCT/US00/09529

(22) International Filing Date: 9 April 2000 (09.04.2000)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

Not furnished

9 April 2000 (09.04.2000) US

- (71) Applicant: MAZZEI, William [US/US]; 9707 Caminito Suelto, San Diego, CA 92131 (US).
- (72) Inventors: JORDAN, Gregory; 2695 Coventry Road, Carlsbad, CA 92008 (US). VU, An, B.; 320 Pomelo Drive, Vista, CA 92083 (US).

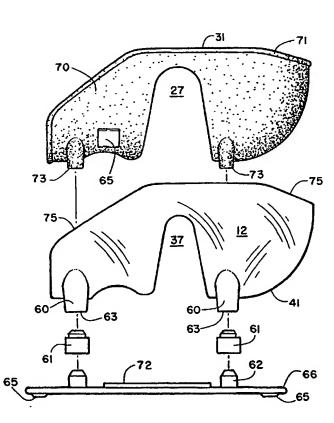
- (74) Agent: HARMS, Donn; Suite 200, 4565 Ruffner Street, San Diego, CA 92111 (US).
- (81) Designated States (national): AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, BS, IT, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

with international search report

[Continued on next page]

(54) Title: PROTECTIVE CUSHION AND COOPERATIVELY ENGAGEABLE HELMET CASING FOR ANESTHETIZED PATIENT



(57) Abstract: This invention is a protective helmet apparatus (10) of modular construction to be worn by anesthetized patients for facial support during surgery. The helmet apparatus is assembled using one of a plurality of interchangeable, substantially transparent helmet casings (12) which are removably attachable to a plurality of dismountable facial cushions (26) (28) (31) providing even support to the facial surface of a patient. The removable facial cushions are dimensioned on an interior surface to accommodate different sized facial structures of different patients to yield maximum pressure diffusion on the face, and chin of the patient that are replaceable when worn. The exterior surface of the facial cushions are dimensioned for cooperative engagement with the interior surface of the helmet casing. A plurality of different facial cushions, helmet casings are modular in design and dimension to be interchangeable with each other, and thus accommodating the broad differences in facial structure, and size of patients using them for surgery.

WO 01/76403 A1

WO 01/76403 A1



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

1 PROTECTIVE CUSHION AND COOPERATIVELY ENGAGEABLE HELMET CASING FOR ANESTHETIZED PATIENT

BACKGROUND OF THE INVENTION

1. Field of the Invention

6

21

The present invention relates to a safety helmet for cranial protection. More particularly it relates to a modular helmet apparatus constructed of interchanging cooperative components of differing sizes which provide a prophylactic cushion and helmet to be worn by patients undergoing general anesthesia to prevent eye, skin, or other nerve damage from prolonged pressure upon areas of the head as well as to provide a safer manner for cranial manipulation during surgery.

2. Prior Art

Surgeries upon patients in the prone position present a number of patient care challenges to the anesthesiologist and surgical staff. Once a patient undergoing a surgery requiring general anesthesia is anesthetized, that patient is essentially in a coma like state. In such a state, noxious stimuli to the patient's body and skin, such as pressure or pain, which would normally cause an awake patient to move to relieve the stimulus, no longer causes such a reaction.

Consequently, patients under general anesthesia are especially threatened by a number of factors, other than the surgery itself, which arise during such surgical procedures.

One hazard which requires constant vigilance by the surgical staff to protect against injury is the threat of eye damage. Inadvertent pressure upon the ocular structures of a patient for just a matter of minutes can cause extreme damage or blindness to the eye. As noted above, because the

anesthetized patient is in a coma like state, the discomfort of facial compression upon the eye, which would normally cause an awake patient to move and relieve that pressure, fails to alert the anesthetized patient. Care must be taken by an ever alert surgical staff to inspect for possible pressure points

about the ocular structures of the patient and to move the

patient's face to prevent eye damage.

21

26

Other compression injuries can occur to the anesthetized patent's forehead and chin areas. Here again, the constant pressure upon those areas, caused by the weight of the patients own head, if not relieved by movement of the face to allow blood flow thereto, can cause localized ischemia to the chin and forehead area. Since the anesthetized patient does not react to the body's cues of discomfort preceding injury, the risk of harm in a matter of minutes to these areas is great.

An additional concern during surgical procedures of the anesthetized patient is the decrease in body temperature that can occur during surgery. Currently bulky warmed towels and electric blankets are used in an attempt to warm the patient. Such endeavors crowd the operating field and are not easily

1 controlled for temperature.

6

26

Currently, there are a number of conventional methods to support the head and protect the eyes and face of a patient from compression injuries during surgery which require the patient to be placed in a prone, face down, position for the long periods of time involved in surgery. One method conventionally used is placement of the patient's head and face in a horseshoe shaped frame supporting a foam pillow which holds the patients face off of the operating table in a supported manner. The patient's eyes are generally taped shut 11 when such a structure is used to keep them from contact with the foam and to prevent eye fluid drainage. This frame and pillow support however has inherent hazards of its own in that it cannot distribute pressure maximally over the surface of the head. Further, great care must be taken by the 16 anesthesiologist and staff to make sure that any anesthetic equipment, such as endotracheal tubes, esophageal stethoscopes, or electronic sensing devices, are not dislodged or disrupted by gravity or patient positioning during the term of the surgical procedure. Such disruption or dislodgement of 21 surgical equipment can cut off the air supply to the patient or lead to inaccurate readings by monitoring equipment.

Another method is simply to place the patient's face sideways on a pillow or towel located upon the surgical table. However, this method suffers from the danger of tubing collapse due to the patient's head weight, and even a face or

eye supported by a foam pillow may be damaged if the pressure is uneven and remains on one area too long. Further, the placement of the patient's face on a towel requires the head to be turned one way or the other, placing pressure on one side of the face which, as noted earlier, subjects the patient to the potential of injury. Additionally, blood flow through the veins and arteries of the neck may be impaired by this twisted fashion of head support. Hazards to the patient increase if the surgery requires a face down posture because the danger of tube collapse from pressure or bending increases 11 with the tubes entering the patient's body through the mouth or nose being compressed between the patient's face and the operating table. With the entry points to the head out of view, such constrictions of the tubes also remain out of sight.

A further challenge facing surgical teams during surgery on anesthetized patients is the seemingly simple task of rolling the patient over from a supine position to a prone position on the operating table or from a cart onto the operating table. Generally, the patient at this point in the surgical procedure is already intubated, asleep, and basically "dead weight." In this physical state, the patient is at great risk of injury during the roll over procedure, especially to the neck area. Additionally vexing to the surgical staff is the fact that the patient, with tubes exiting the mouth and/or nose, must be rolled over, without

disturbing the tubes and without injuring the neck.

Concurrently during the roll over procedure, the surgical staff must plan ahead so that when the patient is placed face down on an operating table, the face is properly aligned with, and inserted upon or into the pillow, already located upon the

- table. This insertion of the face into the pillow is conventionally done without the benefit of a pre surgery fit to make sure the face and pillow and frame mate in a manner that will accommodate the patient for the term of the surgery and protect the face from compression injury. Heads and
- 11 faces being quite different amongst people in general, an optimum fit between face and pillow is achieved only a small percentage of the time. Once in this prone position, the danger of injury remains constant and continued and consistent vigilance by the surgical staff is required to ascertain, that
- in fact, the patient's airways are open, the eyes are not compressed, and the face is not being subjected to pressure at any point for a duration sufficient to cause nerve damage.

Finally, when the operation is over, the patient must again be moved off of the operating table and is generally rolled over onto a gurney in a reverse roll over procedure. Still anesthetized, the patient is at great risk of injury to the neck if the head is not adequately supported and manipulated during this roll over process.

21

Still further, if an emergency develops while the patient 26 is in the face down prone position, requiring the patient to

be rolled to the supine position, valuable life saving time can be lost trying to upright the patient without injury to the neck, and without crimping the airway supply tubing and monitoring equipment communicating through the nose and mouth of the patient.

- Further, patient size is also a factor in the fitting of facial and head support. A child may have a very small face and head and an adult a large one. Conversely, a large child may have a head and face requiring support in areas much different from a small stature adult.
- 11 U.S. Patent 5,220,699 (Farris) teaches an inflatable pillow mounted inside a mask for variable support of differing sized patients. However Farris requires the use of an inflatable chamber which as taught is inflated once the patient has already been rolled to the prone position. It requires an air inflation device to function and lacks the ability for an easy installation prior to surgery and will not function without compressed air.
- U.S. Patent 4,400,820 (O'Dell) teaches an apparatus using pads and having a "T" shaped void which may be used in

 21 combination with a support structure to hold the patient's head. However, O'Dell does not allow for pre-fitting and pre-installing the protective device prior to surgery and does not aid in protecting the patient during roll over on and off the table.

1 U.S. Patent 5,214,815 (Agbodoe) teaches a surgical headrest with a removable foam pad; however, Agbodoe does not provide any manner to pre-fit and install the device on the patient prior to being asleep and it mounts to the table and is intended for use after roll over thereon.

U.S. Patent 4,757,983 (Ray) features a pair of cushions attached to a horseshoe-shaped frame for surgical head support. However Ray also suffers from an inability to pre-fit and install the device on patients prior to surgery while they are awake as well as lacking any protective ability during dangerous roll over onto the table and like the aforementioned prior art, lacks the ability to see the patient's eyes and face from the side or from above.

16

21

26

As such, there exists a need for a support device that is easily modified to fit a variety of patients of differing size, and that may be pre-fit to the patient prior to surgery while the patient is alert and able to ascertain the comfort or discomfort level of the device. Further such a device should provide an additional manner to support the head and maximally diffuse pressure over a large area while helping prevent patient thermal heat loss during surgery, as well as during the hazardous movement of the patient prior to and after surgery. Such a device should also provide for easy viewing of the patient's eyes and nose from a side and top view during the operative procedure so that the patient may be continually monitored by the staff.

A further need exists for such a device that may be cooperatively engaged with a positionable mount or used by itself if needed yet still provide a view of the eyes and ocular area of the patient from looking inward from the side.

SUMMARY OF THE INVENTION

6

The present invention relates to a new and improved protective helmet apparatus which provided functionally through the ability to vary the configuration for the physical characteristics of patients undergoing general anesthesia 11 during surgery, and provide optimum cranial support to the patent using differing configurations of the various parts of the device. Concurrently, the device, when using a substantially transparent helmet casing and operatively placed apertures provides the medical professionals operating on the patient, easy viewing of the patients facial features and easy 16 access to the nasal and oral passages of the patient in either the prone or supine position. The device is best made of modular construction allowing for the substantially transparent helmet casing to fit a variety of different sized 21 patients. Interchangeable and replaceable cushions of variable dimensions on one surface to accommodate different patient facial structures are positionaable in a plurality of interchangeable light weight helmet casings. The cushions on their exterior surface are dimensioned for a registered fit with the helmet casing surface and apertures in the cushion 26

register with apertures in the helmet casing. The cushions can also be color coded to designate different sizes to accommodate different sized patients. If desired, while not the best mode for maximum support and positioning, the cushions themselves can be used without the helmet casing, yet still provide a side view of the patient's eyes and temple area during the procedure through an aperture communicating through a sidewall to the face of the patient. Such might be the case in emergencies when sufficient helmet casings are not available or when a low mount of the patient's head is

The device is especially useful in that it allows for pre-fitting of the patient while the patient is awake and alert using modular pads of differing facial dimensions and having a rear or mask side dimension configured to fit into a registered position in the helmet casing. While the current best mode combines the proper sized cushion with the appropriate helmet casing for a mount on the table surface, even using the facial cushion by itself, if desired, yields a substantial increase in utility over prior art due to the viewing of the patient's eyes and temple area from the side afforded by the apertures therefor. The device having the pre-fitted cushions or pads mounted into the helmet casing, and featuring appropriate indentations on the facial contact surface, evenly diffuses pressures on the face of the wearer and may be worn into surgery such that the surgical team need

16

21

26

not worry about trying to fit the patient with pillows or pads in a table mounted frames after the patient is asleep.

For use in a variety of patients in prone or supine positions during surgery the various embodiments of the device offer a plurality of ways in which to support the patient's head. One embodiment features a hinged or optionally removable lower chin support which is moveable from a first position in operable contact with the helmet casing to a second position out of such contact, thus allowing the surgical team easy access to the entire face and mouth area 11 for insertion of required tubing into the patients mouth and/or nose. The chin support is thereafter reinstalled to provide lower chin support with the entire helmet being worn by the patient for the rollover procedure on and off the table to protect the patient from injury during the course of the 16 surgical procedure. Or, the chin support may be provided by the cushion itself with the cushion and the helmet casing extending below the mouth area of the patient thus eliminating the detachable chin support.

As the device may be pre-fitted for optimal weight

21 diffusion and comfort and can be worn during the movement of
the patient on and off the operating table, the surgical team
is relieved on concerns of whether the device to hold the face
and head actually fits the patient. Further, an optional
rotating handle upon the top of the helmet provides a handy

26 gripping point for the head for the surgical team to help

prevent neck injury during roll over of the patient on and off the table. By placement of a hand on the face of the mask and another on the rotating handle, smooth and continual support may be provided to the neck and head area when the patient is being rolled over on or off of the operating table.

6 Another embodiment of the device features a helmet casing, which is best made of substantially transparent material, having an interior cavity that is formed to register with a cooperatively engageable cushion. The cushion is made from foam or other soft resilient material and is dimensioned 11 on one surface to accommodate the patient's face, and on the other opposite or exterior surface, to register with the interior cavity of the helmet casing. A raised border about the exterior surface perimeter of the cushion could be formed during manufacture to provide an additional means to register 16 and align the cushion with the openings in the helmet casing. Optionally, the cushions may be color coded for patient facial sizing. One or a plurality of apertures communicating through the helmet casing register with appropriately configured apertures communicating between the two surfaces of the 21 cushion and provide an in line cavity from the patient's face through the casing. This in-line cavity provides access to the patient's mouth, nose, and eyes. By dimensioning the cavity to extend around the patients face at eye level, easy viewing of the patient's eyes and nose is provided to the 26 operating room staff.

An additional embodiment of the device would feature a plurality of legs on the exterior surface of the helmet casing to provide a raised mount above the operating table. The legs can be adjustable for height above the operating table to provide comfortable posture to the patient while affording the best access and view of the face of the patient to the staff of the operating room.

11

16

21

26

In the current best mode, an optional base may also be provided which provides a releasable but solid mount for the helmet casing using cooperating fasteners located on the mount and the exterior of the helmet casing. The mount acts as a positioner by providing a stable mount for the helmet casing and optionally may provide additional utility in the best mode with a surface mounted mirror for providing a reflective view of the patient's eyes and nose to the staff of the operating room while the patient is face down and the staff is substantially in an upright position. This eliminates the constant need for members of the operating team to bend over to inspect the face and eyes of the patient during surgery in providing a continuous view of the eyes and face of the facedown patient. Additional utility is provided by an optional light means positioned on the upper surface of the mount adjacent to the mirror by illuminating the patient's face through the in-line cavity and enlightening the reflection on the mirror for the staff to more easily view it from a distance.

An object of this invention is to provide a helmet which prevents injury due to ocular compression during surgery by minimizing ischemic damages through maximal diffusion of pressure about the patient's head.

Another object of this invention is the provision of a protective device for use during surgery which allows for prefit of the patient prior to surgery while the patient may comment on the comfort or discomfort level of the device.

A further object of this invention is to provide a protective helmet for surgery which provides a facial and chin support to the patient which is easily removable by the surgical team for insertion of required devices into the mouth and nose of patient and thereafter easily reinstalled.

11

16

21

26

An additional object of this invention is the allowance of easy access to and viewing of, the patients eyes and temple area through apertures in the device positioned to accommodate such access and viewing.

Another object of this invention is the provision of a protective surgical helmet of modular construction which allows for positioning of different sized facial cushions and components into the helmet casing to accommodate the head different sized patients.

An additional object of this invention is providing an easily sterilized protective helmet through the use of easily sterilized cushions or inexpensive throw away insertable cushions removably mountable inside an easily sterilized or

1 cleaned helmet shell.

11

16

26

A still further object of this invention is to concurrently provide easy viewing of the eyes and mouth area of the patient while the device is mounted upon the patient.

A still further object of the invention is the provision of the ability to control and alter the temperature of the device to aid in temperature control of the patient during surgery.

An additional object of this invention is to provide easy viewing of the patients facial features to the operating staff using while concurrently allows the staff members to remain substantially upright through the provision of a reflective means of the face of the patient.

Further objects of the invention will be brought out in the following part of the specification, wherein detailed description is for the purpose of fully disclosing the invention without placing limitations thereon.

BRIEF DESCRIPTION OF DRAWING FIGURES

Figure 1 is a perspective frontal view of the protective 21 helmet device showing the chin support in a mounted position.

Figure 2 is a frontal view of the device featuring the hinged repositionable chin support.

Figure 3 is a rear exploded view of the protective helmet device showing the modular pads for the ocular area and chin support.

Figure 4 shows the helmet with detachable and repositionable chin support portion.

11

21

26

Figure 5 depicts the helmet with detachable and repositionable chin support slidably mountable to the helmet.

Figure 6 depicts a side view of the apparatus showing the optional handle side grip and the flat face for secure positioning on the surgery table.

Figure 7 depicts another embodiment of the device featuring an exploded view a helmet casing of unitary construction with insertable modular pad providing facial and chin support in a single combined unit.

Figure 8 depicts the helmet casing of figure 7 in a registered position removably or otherwise attached to a mount with optionally mirrored surface for reflection of the patient's face therein.

Figure 9 is a top perspective view of the facial cushion showing the facial indentation and apertures therethrough.

Figure 10 depicts and end cut away view of the facial cushion for removable mounting to the helmet casing showing the facial indentation formed to accommodate patient facial structures therein, and the lip for registration with the casing edge.

Figure 11 depicts a bottom perspective view of the helmet casing showing the unitary construction and the legs affixed to the exterior which provide an elevated mount along with the communicating aperture through the casing.

Figure 12 depicts a top view of the mounting base for the helmet casing with a surface mounted mirror and light source.

Figure 13 depicts a side view of the mounting plate with a mirror and cooperatively engageable mounts on the upper surface.

Figure 14 is a top view of the upper surface of the mounting plate showing the mirror and mounts.

Figure 15 is a tope view of the removably attachable heating blanket with temperature control and clip.

11 DETAILED DESCRIPTION OF THE PREFERRED

16

21

EMBODIMENTS OF THE INVENTION

Referring now to the drawings, Figure 1 depicts a preferred embodiment of the modularly assembled protective surgical helmet apparatus 10 featuring the helmet casing 12 which is best made from a substantially rigid but easily molded material such as plastic. The plastic casing should also be resistant to the heat or chemicals sufficient to allow for sterilization between uses. The modular version of the helmet casing 12 mates with a chin support 14 using conventional registering mating positioners such as

registration pins 16 which correspond to apertures 18 upon the helmet casing 12. Of course the registration pins 16 and apertures 18 might be reversed in positioning or other conventional means of registration and dismountable attachment may be used to achieve a properly aligned mounting of the chin

support 14 to the helmet casing 12. Alternatively, the chin support 14 can be slidably mounted to the helmet casing 12 using a cooperating pair of slide mounts 53 and 51 depicted in figure 5 wherein the chin support 14 with one half of the fastener slid mount 53 would be lined up with the helmet

- casing 12 and cooperating slide mounts 51 and 53 and thereupon the chin support 14 would slide onto the helmet casing 12 by pushing it into position and interfacing the cooperating slide mounts 51 and 53. Cooperating fasteners 20 and 22 in the two-piece embodiment, such as hook and loop fabric, are used to
- maintain the chin support 14 in operative contact in a first position wherein it is in a removably fixed position upon the helmet casing 12, however, other conventional mating fasteners such as plastic or metal releasable locking fasteners can also be used and are anticipated. Cooperating fasteners 20 and 22
- would also be used to maintain the hinged chin support 14 and slidable chin support 14 in the first position of operable and registered contact with the helmet casing 12 although in the case of the slidable version friction alone in the cooperating slides may be sufficient to releasably hold the chin support 14 in proper contact with the helmet casing 12.

The dismountable chin support 14 may also be attached to the helmet casing 12 at one end using a conventional metal or plastic hinge fastener 34 such that the chin support 14 will swing away from its first position in operative contact in a

registered mounting with the helmet casing 12. This
embodiment allows for easy access to the patient's facial area
during surgery or emergencies while maintaining the chin
support attached to the helmet casing 12 when swung to the
second position out of operative contact with the helmet
casing so as to avoid loss of the chin support 14.

Straps 24 having cooperating fasteners 25 at their distal ends securable to mating cooperating fasteners 25a upon the helmet casing 12 may be optionally used to secure the helmet casing 12 upon the face of the patient once the properly sized ocular cushion 26 has been removably mounted into the helmet casing 12.

11

16

21

In certain instances the helmet casing and chin support might also be formed as one piece for surgeries where a removal of the chin support 14 is not a major consideration and for ease of use and reduction in parts to inventory. In such a one piece embodiment the support to the face of the patient provided by the ocular cushion 26 and chin cushion 28 would be provided by a single once piece facial cushion 31 which is configured to removably mount into a one piece embodiment of the helmet casing 12 in a registered position, therein thereby providing stable even support the entire face of the patient from forehead to chin. In the one piece version of the helmet casing 12 the front surface would be extended to a point below the chin and thereby accommodate a

once piece facial cushion 31 and apply complete support to the head of a patient.

The ocular cushion 26 and chin cushion 28, or one piece facial cushion 31, if reusable, are best made of a closed cell foam material or other cushioning material which does not absorb fluid easily to allow the cushions to be sterilized in the conventional fashion for reuse. In many instances sterilization may not be necessary and a simple washing may provide the required level of cleanliness. In such cases the material used will be durable for reuse and resistant to cleaning to allow multiple uses of the cushions 26, 28, or 31. 11 However, for ease of use and to maintain a highly sterile field about the patient, disposable ocular cushions 26, chin cushions 28, and one piece facial cushions 31 may be more desirable since they could be used once and replaced after each operation to maintain a highly sterile or sufficiently 16 clean field. The best mode as to disposable or reusable is best determined by the criteria of the hospital or surgery center involved and their individual criteria.

Optionally, for an even more custom fit to individual

21 patients is desirable, the ocular cushion 26 and chin cushion

28 or the once piece facial cushion 31 may also be made

inflatable with gas or fluid or silicone or other gel such

that they may be adjusted in size and flexibility by filling

them with a gas or liquid into the cushions through a sealable

26 orifice communicating through the wall of the cushion.

The ocular cushion 26 may be made in a set of multiple 1 ocular cushions 26 varied in dimensions of both thickness and width and have variable sized and located ocular apertures 27 therein to best accommodate the size and facial structure of a variety of differing sized individuals using the same helmet casing 12. The chin cushions 28 may also be from a set of such chin cushions 28 varied in dimensions of both thickness and width to achieve optimum fit on individual patients. The one piece facial cushion 31 used with the one piece embodiment of the helmet casing 12 provides the same adjustable utility and can be varied in the same fashion by providing multiple facial 11 cushions 31 for use as a kit to be combined with one piece helmet casing 12. The facial cushion 31 has a facial indentation 35 formed on a first side of the facial cushion 31 sized to accommodate the face size of the intended patient. The opposite side or exterior surface 38 of the facial cushion 16 31 would be dimensioned for cooperative engagement with the interior surface 35 of the one piece embodiment of the casing 12. By varying the dimensions of the cushions 26 and 28 or 31, and the size and location of the apertures therein, and 21 matching them to the properly sized one or two piece helmet casing 12, virtually any adult or child may be fitted to wear the resulting assembled device 10 comfortably with optimal support of the facial structure of the cranium and maximal diffusion of pressure and weight about the face and sides of

the patient's head to obviate injury to the eyes and face and nerves.

In the two-piece embodiment, the ocular cushion 26 and the chin cushion 28 are attached to the helmet casing 12 and repositionable chin support 14 respectively, using a means of attachment such as corresponding mounts 32 formed of hook and loop fabric or adhesive pad fasteners mounted on the cushions 26 and 28 in positions to contact corresponding cooperating mounts 33 on the respective interior surfaces 35 and 36 of the helmet casing 12 and chin support 14. However, adhesive mounting does not require using cooperating mounts 32 and 33. In this manner using adhesion, adhesive, two-sided tape, adhesive pads, adhesive covered by an easily removable paper, or similar conventional adhesive attachments can be placed between the cushions 26 and 28 and the inside faces of the helmet casing 12 and chin support 14. A frictional engagement between the facial cushion 31 and interior surface 35 of the one piece embodiment of the helmet casing 12 would also provide a means of attachment therein using the weight of the patient's head to maintain registration of the facial cushion 31 in the casing 12 and in such a use of components optional retaining tabs 43 could be provided as an additional means of attachment of the facial cushion 31 to the helmet casing 12 to insure that it stays registered therein.

11

16

21

adhesive or other means for a removable attachment can be placed upon the helmet side of the respective cushion surface for an easy mount of the cushions into the helmet casing 12 and/or repositionable chin support 14. Such a disposable form of cushions 26, 28, and 31, would be kept sterile inside a sealed wrapper in the conventional manner and removed and mounted to the inside face or interior surfaces 35 and 36 of the helmet casing 12 and chin support 14 respectively as necessary in the configuration decided upon, using 11 conventional peel and stick adhesive pads positioned upon the surface of the cushions to attach them to the helmet interior surface 35.

The device 10 offers great utility to the user since it is capable of using either disposable or reusable cushions for cushions 26, 28, or 31, or combinations thereof at the discretion of the professional using the device. Where disposable cushions are desirable due to their ease of use and lack of the need for sterilization, just the helmet casing 12 and chin support 14, if used, need be sterilized. Or, in the case of the once piece casing just the casing need be sterilized if required. However, a reusable form of cushions 26, 28 and 31 may also be used in the device 10 where the cushions can be sterilized between use, or, in instances where sterilization is determined not to be needed they need only be

16

21

washed. Or, a combination of reusable and disposable cushions
26, 28 and 31 may be used should such be desired or required
if a reusable cushion is lost or damaged.

In use, with the two-piece embodiment, the patient would be measured for the optimum helmet casing 12 size which would be chosen from a plurality of available interchangeable helmet 6 casings available, and, a chin support 14 of proper size which would be chosen from a plurality of interchangeable chin supports capable of attachment to said casing 12. Also chosen to accommodate differing facial and head dimensions would be 11 the properly dimensioned cushions 26 and 28, from a set of interchangeable cushions, to allow the patient maximum comfort and diffusion of pressure about the surface of the face and side of the head. The patient could be given samples of the different sizes of cushions 26 and 28 from a set of variable 16 dimensioned cushions 26 and 28 to which the patient would give input as to the best possible fit or a medical technician might also help determine the optimum casing and cushion dimensions with or without the patient's input. This availability of an assortment of cushions and assembled helmet 21 sizes allows for a modular system of helmet casings 12 and attachable chin supports 14 assembled to the helmet, to be used in conjunction with the desired dimension of cushions 26 and 28, also from a set of such cushions of differing dimensions, to achieve the optimum fit on a variety of sizes

1 of patient heads.

11

16

21

Once the optimum dimensions of the cushions 26 and 28 are determined, yielding a comfortable fit and maximal pressure distribution about the face and sides of the head, the cushions 26 and 28 are removably mounted into the interior of both the helmet casing 12 and chin support 14 using the aforementioned adhesive or fastener cooperating mounts 32 located upon the cushions which attach to cooperating mounts 33 which are positioned upon the helmet casing 12 and chin support 14 respectively. This is accomplished in a manner to allow for the mounting the cushions 26 and 28 into the cooperatively configured interior surfaces 35 and 36 of the helmet casing 12 and chin support 14 respectively.

The inside surface 35 of the helmet casing 12 features a casing ocular aperture 37 and the chin support 14 has a chin support aperture 39. When properly positioned in the cooperating inside faces of the helmet casing 12, the aperture 27 in the ocular cushion 26 will be relatively in line with the casing ocular aperture 37 such that the eyes and nose and some surrounding portions of the patient's face, or the ocular area of a patient's face, may be easily viewed through the ocular aperture 37 when the device 10 is being used during surgery after being positioned upon the patient's face. The ocular aperture 27 might best be made slightly larger than the casing ocular aperture 37 to allow for easy mounting of the

1 ocular cushion 26 into the helmet casing 12 to allow for the patient's eyes and surrounding skin area to be viewed through the casing ocular aperture 37 and relatively in-line cushion ocular aperture 27. Where the casing ocular aperture 37 wraps around to the side of the helmet casing 12, the in-line ocular cushion aperture 27 would also wrap around in a relatively inline position with the casing ocular aperture 37. This in line relationship of apertures creates a viewing passage communicating through the helmet casing 12 and apertures 37 and 27 thus revealing the patient's temple area of the head in 11 addition to the ocular area of the face and the nose. line relationship of the apertures of the cushions 26 and 28 with the casing apertures 37 and 29 also allow for the passage of conventionally used tubes through the in line apertures into the patient's nose and/or mouth for providing life 16 support during the operation. Further, the cavity formed by the in line cushions 26 and 28 attached to the helmet casing 12 and chin support 14 gives protection to these tubes at the critical entry and exit positions on the patient at the nose and mouth such that the tubes, inside the cavity, will not 21 bend to a point where flow therethrough is interrupted with possible life threatening consequences to the patient. For additional utility, optional tube passages 44 communicating a tubular passageway from the interior of the device 10 to the exterior, can provide for communication of tubes or sensing

device wires therethrough to the patient. Exterior mounted optional tube positioners 46, of hook and loop fabric or other type of fastener suited to the job, can be optionally mounted upon the exterior of the device 10 to hold tubing and/or wires for monitoring the patient operatively therein during surgery.

6 Snap on fasteners may also be optionally attached at the exterior of the device 10 to hold tubing and the like. By providing optional strategically placed snap mounts 48 the snap on fasteners may be placed in differing positions about the exterior to hold the tubing and/or wiring required for certain surgical procedures in place and out of harms way.

The chin support aperture 39 of the two-piece embodiment lines up with the bottom of the casing ocular aperture 37 when the dismountable chin support 14 is operably mounted to the helmet casing 12. The chin support aperture 39 allows for viewing and access to the lower mouth area of the face of the patient with the chin of the patient being supported by the chin aperture 29 in chin cushion 28 removably attached to the interior surface 36 of the chin support 14.

16

Added utility is provided by the device 10 operably

21 mounted to the face of the patient using attributes of the
frontal surface 41 of the device 10. This frontal surface 41

if made flat like that of the upper table surface 64 of a
conventional operating table, allows for a stable support of
the patients face inside the properly mounted device 10 when

the frontal surface 41 is placed upon the operating table without a mount if such a positioning is desired. For especially stable maintenance of the patient's head when in a sideways position a second side flat surface area on the sidewall 47 area may be located on one or both sidewalls 47 of the device 10.

Or, as depicted as the one-piece embodiment of the device in figure 7, legs 60 attached to the casing exterior surface 49 can provide both a means for elevation of the helmet casing 12 above the couplings 62 on the mounting plate 66 and 11 underlying table surface 64 and if desired, registration using at least two of the couplings 62. The couplings 62 as depicted, are dimensioned to cooperatively engage the distal ends of the legs 60 and can be mounted directly to the operating table surface 64 using a means for attachment to the 16 operating table surface 64 such as adhesive 65, frictional engagement, or other means of attachment to the table surface 64. Or in the current best mode a mounting plate 66 would have the couplings 62 mounted thereon positioned to provide a registerable mount through cooperative engagement with an 21 axial leg aperture 63 in the distal end of the legs 60. Insertable leg extensions 61, made of differing lengths to achieve the desired elevation, provide an adjustable means for elevation would fit between the leg apertures 63 and onto the couplings 62 providing a means for height adjustment of the

helmet casing 12 above the underlying table surface 64 to accommodate various posture positions for the patient's head and neck.

The single piece embodiment of the helmet casing 12 features a front wall surface 41 which extends laterally and then curves to a pair of side walls 47 both of which begin at one side with their communication with the front wall surface 41 and extend vertically at an acute angle from the front wall surface 41 to form the two substantially parallel sidewalls 47. In this embodiment the casing ocular aperture 37 in the 11 current best mode, is enlarged and extended around and through the front wall surface 41 and upward onto and through at least one side surface 47 of the helmet casing 12 providing a clear view of the patients eye, and face in the temple area, as well as the area in front of the nose, from one or both sides of the device 10. Extending the casing ocular aperture 37 and 16 the cushion ocular aperture 27 up at least one sidewall 47, whether they are used in combination or when the cushion might be used by itself, thus provides a means to view the eye socket and surrounding area through the sidewalls 47 of the device of the patients who might use the device. current best mode, the ocular apertures of both the once piece helmet casing 12 and the facial cushion 31 extend up both sidewalls 47 to provide a viewing passage 82 of both eyes and the surrounding temple area of the head of the patient through

the sidewalls 47. Viewing of the temple area is also achieved through the transparent material making up the helmet casing 12 and would allow for a larger ocular cushion aperture 27 to provide more of a view of this area thus allowing even greater viewing of the patients eye area much like a window.

6

11

21

26

During times of moving of the patient for roll over or off of the surgical table and onto a gurney, an optional top handle 40 attached to the top area of the helmet casing 12 portion of the assembled device 10 allows medical personnel a solid griping point for providing head and neck support to the patient while being rolled over or otherwise moved. holding the patient's neck with one hand and the handle 40 in the other, essential support can be provided to avoid injury to the anesthetized patient. A roller or ball or other conventional bearing 42 can also be placed at the base of the 16 handle 40 should easy rotation of the handle 40 be desired during use. Such a rotation of the handle 40 on the bearing 42 allows for a smooth roll over of the patient with the patient's neck concurrently supported, thus minimizing possible neck injuries during roll over and other hazardous patient relocation procedures.

Additional utility in the disclosed apparatus herein is provided by the insulating factor provided to the patient wearing the surgical helmet 10 and cushions 26, 28, and 31, when mounted upon the face of the patient during a surgical procedure. Operating rooms are conventionally kept quite cold

to keep medical personnel and surgeons cool and alert during surgical procedures. The patient however is generally unclothed during such procedures and can suffer discomfort from the overly cool environment of the room. The cushions 26, 28 and 31, form to the face of the patient and are mounted upon the interior surface 35 of the device 10, and thereby encompass the face and part of the sides and top of the head of the patient. The result being that the face, sides, and top of the patient's head are insulated from the cool room temperature, helping to keep the patient warmer in the unnaturally cool environment of the operating room.

Further utility is also provided by this surgical helmet device 10 through the use of optional slot passages 45 located in the face of the device for positioning of tubes therein.

During a surgery requiring the patient to lay face down, tubes providing breathing supplies to the patient may be positioned in a slot configured to allow the tube to recess therein such that the tube will not collapse when the patient is face down and the tube is between the table and casing exterior surface 49 of the device 10. Such a slot passage or multiple slot passages 45 may be positioned about the face of the helmet in other locations than shown.

16

21

26

Figure 7 depicts a preferred embodiment of the device 10 featuring an exploded view showing the helmet casing 12 of a one piece or unitary construction. In this embodiment, the casing walls are best constructed of rigid substantially

transparent material such as plastic in a unitary construction. This embodiment provides the same desired support for the chin and face provided by the two-piece embodiment accomplishing this support with a cooperatively engageable once piece facial cushion 31. This one piece 6 embodiment continues to provide proper chin and face support by slightly elongating the helmet casing 12 in a one piece design and combining the ocular cushion 26 and chin cushion 28 into a one piece facial cushion 31 which is dimensioned on the exterior surface 70 of the facial cushion 31 for cooperative 11 engagement with the interior surface 35 of the helmet casing The facial cushion 31 is dimensioned on the interior surface 69 to provide a comfortable fit to the face of the patient for which it is to be used. In use, in essentially the same manner as the two-piece embodiment, the intended 16 patient would be measured for the optimum facial cushion size 31 which would be chosen from a plurality of available interchangeable facial cushions 31 available for registered cooperative engagement with the one piece helmet casing 12.

In many cases only one or two different sized helmet casings 12 would be needed in inventory to be mated with cushions to accommodate a very large number of differently dimensioned facial cushions 31 since the size, thickness, and exterior and interior dimensions of the facial cushion 31 may be varied to accommodate the different facial dimensions of

21

different patients. This is accomplished by the variance of the dimensions of the indentations 68 formed on the interior surface 69 of the facial cushion 31 which are used accommodate the facial dimensions of the intended patient. The exterior surface 70 of the facial cushion 31 would be dimensioned for operative cooperative engagement with the shape and dimensions of the interior surface 35 of the helmet casing 12 in the aforementioned registered and cooperative engagement therein.

The registration and cooperative operative engagement between the cushion 31 and helmet casing 12 would be 11 maintained using a means for registered engagement of the facial cushion 31 with the helmet casing 12 which includes one, or a combination, of registration means, from a group of such registration means consisting of frictional engagement between the interior surface 35 of the helmet casing 12 and 16 exterior surface 70 of the facial cushion 31, adhesive 65, a lip 71 located about the upper exterior surface 70 of the facial cushion 31 in a position to cooperatively engage the upper edge 75 of the sidewalls 47 of the helmet casing 12, or, registration pins 73 attached to the body of the facial 21 cushion 31 in positions to cooperatively engage registration apertures in the casing, in this case axial passages 77 formed into the legs 60 and sized to accept the registration pins 73 in a removable cooperative engagement. Since the registration pins 73 would in the current best mode be molded of the same

flexible foam as the facial cushion 31 they offer the current best mode of registration since the registration pins 73 will compress during insertion into the axial passages 77 and then naturally bias against such compression into removable biased frictional engagement with the interior of the axial passages

77. While the aforementioned are the current best mode of a registration means between the facial cushion 31 and the helmet casing 12, those skilled in the art may devise other such means of registered engagement and such are anticipated.

11

16

21

In fitting the patient for maximum comfort and support, the patient could be given samples of the differently dimensioned facial cushions 31 from an available plurality or set of variably dimensioned facial cushions 31 to which the patient would give input as to which formed indentations 68 provide the best possible fit to the facial dimension of the patient. Or, a medical technician might also help determine the optimum helmet casing 12 and facial cushion 31 dimensions with or without the patient's input. This availability of an assortment of differently dimensioned facial cushions 31 to cooperatively and operatively engage one or a plurality of helmet casings 12, allows for a kit or modular system of helmet casings 12 and attachable to facial cushions 31 to achieve the optimum fit on a variety of sizes of patient For easy identification of size the facial cushions 31 would be marked with appropriate indicia 30 in writing showing

the form of color coding for easy identification. The color coding or written indica 30 to identify size could be imparted by extruding it in the color of the foam making up the facial cushion 31 or silkscreened or otherwise applied on the surface of the cushions 26, 28, and 31. Once the optimum dimensions of the facial cushion 31 are determined, yielding a comfortable fit and maximal pressure distribution about the face and sides of the patient's head, the facial cushion 31 is removably mounted to the interior of the helmet casing 12 using the aforementioned means for registered engagement of the facial cushion 31 with the helmet casing 12.

The one piece facial cushion 31 offers an additional benefit in that in some cases it might be used without the helmet casing 12. Use without the casing might occur when an especially low mount of the patient's head is desired for posture or for the surgical procedure, or, in an emergency or other situation where the additional support and utility of the in-line helmet casing 12 is not required. Use of the facial cushion 31 by itself, while not offering the full utility of the best mode in combination with the helmet casing 12, does provide the easy side viewing of the patients eyes through the elongated ocular cushion aperture 27 and still provides improved support and padding to the patient's head during surgery. Consequently, it is anticipated that the

16

21

1 cushion might be used alone without the casing 12, and while not providing all of the utility of the device featuring the combination of the facial cushion 31 with the helmet casing 12, using the cushion alone would still provide much better support to the patient's face, a clear view of the eyes through the elongated cushion ocular aperture 27 and a solid support to the patient's head on the table through frictional engagement therewith.

Or, in some cases, where reuse of the cushion may not be advisable due to the patient, the helmet casing 12 might also 11 be formed into the exterior of the facial cushion 31 itself. This could be done if a substantially rigid shell 80 were formed about the exterior surface 70 of the facial cushion 31 by either lamination thereto or in the molding process and would provide rigid support to the facial cushion 31. However 16 this configuration with the helmet casing 12 as attached to the facial cushion 31 as a laminated or permanent shell yields less utility in that different facial cushions 31 for different sized patients could not be matched to a single helmet casing 12 thus requiring more stock of product. But, 21 differing user criteria and requirements may call for the facial cushion 31 to be thus used and manufactured with a casing formed by the rigid shell 80 formed on the outside surface for use without the additional advantages afforded by mating with the helmet casing 12 and such is anticipated.

While the current best mode of the device, affording the most utility, is the registered engagement of a properly sized facial cushion 31 with the helmet casing 12, the cushion-only embodiments offer the operating staff the option to use the facial cushion 31 without the helmet casing 12 and still achieve much better support of the patient's head, thermal insulation and view of the patient's eve and surrounding

insulation and view of the patient's eye and surrounding temple area 74 which is a marked improvement to the current practice of placing the head on a towel. The very nature of the exterior surface 70 of the soft foam facial cushion 31 would provide a good frictional mount to the surface of the

would provide a good frictional mount to the surface of the table surface 64 and good side and frontal support to the head of the patient with a concurrent view through the elongated casing ocular aperture 37 reaching around the side to allow a view of the patient's eye socket from an operative distance.

16 Use of the facial cushion 31 could also occur if there were a shortage of helmet casings 12 for the number of patients requiring surgery during an emergency situation. Consequently it is anticipated that the facial cushion 31 could be used by itself in certain instances and would still be a substantial improvement for a mount and support of the patient's head than

To provide an excellent view of the patient's facial features, as with the two piece embodiment, the interior surface 35 of helmet casing 12 features a casing ocular aperture 37 communicating through the casing front wall 41

the present art.

26

surface and side walls 47 and the chin support aperture 39 formed into the front wall 41 surface and communicating therethrough. The one piece embodiment the helmet casing 12 as noted also features an elongated casing ocular aperture 37 which wraps around the helmet casing 12 to determined

الأفاق المرابع والمناهد المرابع المناهد والمناهد والمناهد المناهد المناهد المناهد المناهد والمناهد المناهد الم

- termination points in one or both substantially parallel side walls 47, and thus allow for easy viewing of the eye area of the patient during use by looking through the in line casing ocular aperture 37 and cushion ocular aperture 27. In the one piece embodiment this casing ocular aperture c communicates
- with the chin support aperture 39 to yield a somewhat figure eight shaped aperture when the casing is viewed from the bottom. The in line ocular cushion ocular aperture 27 where it intersects the cushion chin support aperture 39, yield a nasal cavity 57 the area of which is defined by the thickness of the wall surface of the facial cushion 31 and the perimeter.
- of the wall surface of the facial cushion 31 and the perimeter of the intersecting chin support aperture 39 and the cushion ocular aperture 27. Along with providing a passageway for tubes to the patient, the nose cavity 57 also yields a good view of the nose and facial area around the nose when the patient is in the prone position, providing additional utility to the device.

When properly positioned, the cooperating engagement of the facial cushion 31 and helmet casing 12, will place the cushion ocular aperture 27 substantially in line in a

registered position in relation to the casing ocular aperture

37. The ocular cushion ocular aperture 27 might best be made
slightly larger than the helmet casing ocular aperture 37. This
slight increase in size provides for easy mounting of the
facial cushion 31 into the helmet casing 12 to a position to

allow the patient's eyes and surrounding skin area to be viewed through the wrap around casing ocular aperture 37 and relatively in-line cushion ocular aperture 27. When the helmet casing 12 is substantially transparent material, as in the current best mode, the increased size of the apertures of the facial cushion 31 also increase the area around the eyes and nose of the patient that can easily be viewed since these areas may be viewed through the helmet casing 12 itself.

As noted, in the current best mode, the casing ocular aperture 37 wraps around from the front to both sides of the helmet casing 12. The ocular cushion aperture 27 would also wrap around substantially the same such that when mounted it would engage the casing ocular aperture 37 in a relatively inline position, registered with the ocular casing aperture 37. A viewing passage 82 provides a means to view the eyes and nose and some surrounding portions of the patient's face through the sidewall 47 is thus defined and provided by the in-line relationship of the wrap around facial cushion ocular aperture 27 and the casing ocular aperture 37 and the cushion chin support aperture 39 and the casing chin aperture 29 thus

16

21

forming the viewing passage communicating through the helmet casing 12 and the apertures in the facial cushion 31 providing an excellent view of the patient's temple area of the head in addition to the ocular area of the face and a nose cavity 57 for accommodating and viewing the nose from both sides of the device and well as from below the device when mounted on the operating table. This in-line relationship of the cushion apertures 27 and 39 with the casing apertures 37 and 29 also allows for the passage of conventionally used tubes through the in line apertures into the patient's nose and/or mouth for providing life support during the operation.

registered in position with the helmet casing 12 which is in a registered position removably attached to an optional mount plate 66 using couplings 62 configured to cooperatively engage the distal ends of the legs 60 which are attached to the helmet casing 12 at their opposite ends. The couplings 62 are depicted as pins that insert into indents in the legs 60 but this arrangement could be reversed with the legs positionable into indents in the mounting plate 66 or other means for attachment of the legs 60 to the couplings 62 could be used and are anticipated. If needed to adjust the height of the helmet casing 12, and thus the height of the head of the patient for comfort or function, one or a plurality of leg extensions 61 may be used to adjust the height as desired. The leg extensions

21

1 **61** would of course be configured to operatively engage in a fit between the legs **60** and the couplings **62**.

The couplings 62 alone using adhesive or other manner of attachment could be pre-installed to the operating table surface 64 in cases where the optional mounting plate 66 is not desired, however in the current best mode, the mounting plate 66 positioned on the operating table surface 64 would provide the couplings 62 attached in positions to cooperatively engage the distal end of the legs 60 to thereby provide a stable means of elevated attachment of the helmet casing 12 above the table surface 64 in registered engagement with the mounting plate 66.

11

By the provision of a means for elevation, through the provision of legs 60 to slightly elevate the helmet casing 12 above the operating table surface 64, and the means for elevation adjustment using the leg extensions 61, or other 16 manner of extending the length of the legs 60 such as telescopic legs, or legs extending with pins to hold the elongation of the legs, better patient posture is achieved by keeping the patient's neck in line. Elevating the helmet casing 12 and patient therein also elevates the casing ocular 21 aperture 37 and casing chin aperture 29 thereby allowing better views therethrough of the patient for direct viewing by the staff. The casing ocular aperture 37 being extended around the frontal area and communicating between the casing interior surface 35 and casing exterior surface 49 and extending to the

side area of the helmet casing 12, provides an easy and clear view of the patients eye and temple area 74. For additional utility, the aforementioned optional tube passages 44 could be operatively positioned in the once piece embodiment of the helmet casing 12 to provide a tubular passageway from the interior of the device 10 to the exterior for the various devices requiring such.

While elevating the helmet casing 12 provides extra room between the table and the in-line apertures to allow better viewing of the patient from the side and below, in the current best mode, the placement of a mirrored surface 72 on the upper surface 67 of the mounting plate 66 provides additional utility through the provision of a means for the upright operating staff to view of the patients eyes and temple area around the eye, through the in line ocular and chin apertures 29 and 37.

- Normally the doctor or staff member wishing to view the patient's eyes area adjacent to the eye temple area 74 or face would have to stoop to an angle wherein they can be seen through the in line apertures in the helmet casing 12 from the side, or in some cases from below the operating table.
- 21 However, with the provision of a mirrored surface 72, operatively placed on the upper surface 67 of the mounting plate 66, the doctors and staff are afforded a means for a continuous real time view while standing, of the patient's eyes and mouth through the apertures 37 and 29 in the helmet casing

Should even more adjustability of the reflection be desired so that certain staff in certain positions can see the patient's eyes and mouth, a means for angular adjustment of the mirrored surface 72 could be attached between the mounting plate 66 and the mirrored surface 72 such as a ratchet 78 or other conventional means for angular adjustment that will provide the user with the ability to adjust the angle of the mirrored surface 72 from substantially parallel to the mounting plate 66 toward a position normal to the mounting plate 66. The mirrored surface 72 with the means for angular adjustment 11 thus may be positioned to an infinite number of angles between positions parallel and normal to the mounting plate 66. Such adjustment provides substantial utility to the operating room staff and doctors by allowing them to adjust the mirrored surface 72 to obtain the best possible view of the patient 16 through the in line apertures of the facial cushion 31 and helmet casing 12.

Should additional enhancement of patient viewing be desired, the addition of the optional illumination means in the current best mode in the form of light 76 which further

21 enhances the reflected view in the mirrored surface 72 by illumination of the patient's facial features which reflect in the mirrored surface 72. The illumination means could be a conventional light bulb, a light emitting diode, or other similar light sources and can be powered by conventional AC or

1 battery power that is readily available in the operating arena.

Construction of the one piece embodiment of the facial cushion 31 and the various options thereto, is best depicted in figure 9 and Figure 10. As shown from the top perspective view of figure 9, the indentations 68 to accommodate various sized

- faces and facial structures are operatively positioned and provide excellent head support in the form of a forehead support 54, cheek supports 55 and chin support 56. The registration pins 73 protrude from the exterior surface 70 in positions to register the facial cushion 31 in operative
- engagement with the leg axial passages 77 extending axially through the legs 60 of the one piece embodiment of the helmet casing 12. Registered insertion of the facial cushion 31 into the helmet casing 12 is thus easily achieved by the in line cooperative engagement of the registration pins 73 with the
- axial passages 77 in the legs 60. Of course the other aforementioned means of registration of the facial cushion 31 with the helmet casing 12 might also be used including the lip 71, adhesive 65, or frictional engagement of the exterior surface 70 of the facial cushion 31 with the interior surface
- of the helmet casing 12. In cases where the additional utility of the helmet casing 12 encompassing the facial cushion 31 is not required the facial cushion 31 could be used alone in a frictional engagement with the surface of the table surface 64.

1 Figures 11 and 12 provides a bottom perspective view and a top perspective view respectively, of the one piece embodiment of the helmet casing 12. As shown, the legs 60 contain the axial passageway 77 therein communicating with an leg aperture 63 at each end for registered engagement of the molded registration pins 73. The elongated casing ocular aperture 37 in the one piece casing extends across the bottom and up both sides of the one piece helmet casing 12, and communicates with the chin aperture 29 to form a single large "t" or figure eight shaped aperture which registers in an in-line relationship with 11 a similar shaped and slightly larger aperture in the one piece facial cushion 31. Also depicted are a pair of optional tube passageways 50 providing communication to the interior of the helmet casing 12 through axial tube passages 52 therein.

A preferred embodiment of the mounting plate 66 component

is depicted in figures 13 and 14. The mounting plate 66 in the
current best embodiment is constructed of rigid plastic such as
polycarbonate which is substantially transparent. A plurality
of couplings 62 are attached to the upper surface 67 of the
mounting plate 66 to provide the registered mount for the legs

21 60 of the helmet casing 12. In this embodiment, rather than
having the mirrored surface 72 on the upper surface 67 of the
mounting plate 66 the mirrored surface 72 is adhered to the
bottom surface 83 of the mounting plate 66. Adhering the
mirrored surface 72 to the mounting plate bottom surface 83

1 facing upward toward the tope surface, allows the mirrored surface 72 to provide the desired reflection of the patients face through the substantially transparent plastic material of the mounting plate 66 while concurrently protecting the mirrored surface 72 from scratching. In this embodiment the
6 mirrored surface 72 may be adhered to the bottom of the mounting plate 66 by using mirror attached into an indent in the bottom surface 83 or by applique of a metalized or reflective surface to the bottom surface 83 such that when viewed through the substantially transparent material making up 11 the mounting plate 66 from the upper surface 67 a reflection is provided. The depicted optional outwardly biased conventional plunger ball 85 would provide additional stability to the couplings 62 in their cooperating engagement with the legs 60.

of the patient is a concern is provided by the optional removably attachable means for heating the head of the patient. In the current best embodiment the means for heating the head of the patient is provided by a removably attachable heating blanket 87 as depicted in figure 15. The heating blanket is removably attachable to the helmet casing 12 using biased clip 90 which is spring loaded and attaches to an upper edge of the helmet casing 12. The heating blanket 87 provides heat using a resistive element 92 which heats the blanket body 93 when power from an electrical power source 94 is communicated thereto

through conventional wires 96. The heat is distributed evenly by the serpentine arrangement of the resistive element 92 thus avoiding hot spots. Control of the amount and duration of heat would be provided by a conventional thermostat 98 engagement with the resistive element 92 to break the circuit when the

- desired temperature is obtained. The wires 96 might also be a flat strip style wire that is appliqued to the exterior surface 70 of the helmet casing 12 and an interface on the clip 90 such that attaching the clip 90 to the helmet casing 12 would also provide power to the blanket 87 through the interface in the
- clip 90. Alternatively, in some cases it may be more advantageous to attach the resistive element 92 by affixing it or appliqueing it to the interior surface of the helmet casing 12 in between the facial cushion 31 and the helmet casing 12 where it would work in the aforementioned fashion but provide heat to the face of a prone patient or the back of the head of a supine patent using the disclosed device.

of the protective cushion and cooperatively engageable helmet casing for anesthetized patient have been shown and described,

21 it should be understood that various substitutions,

modifications, and variations may be made by those skilled in the art without departing from the spirit or scope of the invention. Consequently, all such modifications and variations are included within the scope of the invention as defined by

26 the following claims.

While all of the fundamental characteristics and features

1. A protective helmet apparatus for providing patient cranial support during surgery, which may be assembled from a plurality of cooperatively engageable components of differing dimensions for achieving optimum fit and pressure diffusion upon face of the intended helmet wearer comprising:

a cushion, said cushion having a front portion and two sidewalls extending upward from said front portion, said cushion having a interior surface and an exterior surface;

said interior surface of said cushion dimensioned to accommodate the facial structure of a human being;

at least one cushion ocular aperture in said cushion communicating laterally across said front portion and continuing up at least one of said sidewalls, said ocular aperture providing communication between said interior surface and said exterior surface;

a viewing passage formed by said ocular cushion aperture, said viewing passage providing a view through at least one of said sidewalls, wherein the eye and facial temple area and the eye of a patient wearing said cushion while in the prone position, may be seen though said viewing passage from a position adjacent to at least one of said sides.

2. The device as in claim 1 wherein said exterior surface of said cushion dimensioned for cooperative registered engagement with the interior of a helmet casing whereby said cushion is removably positionable on one of a helmet casing or a mounting surface in a position to provide support to the head of a patient undergoing surgery.

3. The protective helmet apparatus as defined in claim 2 further comprising:

a helmet casing for use in combination with said cushion, said helmet casing having a casing front wall and two casing sidewalls, each of said sidewalls attached at a first edge to said front wall extending generally vertically therefrom to an upper edge of said sidewalls, said helmet casing having a casing interior surface and a casing exterior surface;

means for registered cooperative engagement of said cushion with said helmet casing;

at least one casing ocular aperture in said helmet casing communicating between said casing interior surface and said casing exterior surface, said casing ocular aperture shaped substantially similar to said cushion ocular aperture, and positioned in said helmet casing to align with said cushion ocular aperture when said cushion is in said registered cooperative engagement with said helmet casing, whereby said viewing passage extends through said casing ocular aperture when said cushion is in registered cooperative engagement with said helmet casing; and

means for removable attachment of said helmet casing to a fixed position on a mounting surface.

4. The protective helmet apparatus as defined in claim 3 wherein said means for registered cooperative engagement of said cushion with said helmet casing comprises one or a combination of means for registered cooperative engagement from

WO 01/76403
a group consisting of, said casing interior surface dimensioned for frictional engagement with said exterior surface of said cushion, adhesive, a lip positioned on said cushion in a position for operative engagement with the upper edges of said sidewalls, and registration pins affixed to said exterior surface of said cushion cooperatively engageable with registration apertures located in said interior surface of said helmet casing.

- 5. The protective helmet apparatus as defined in claim 4 wherein said means for registered cooperative engagement of said cushion with said helmet casing is a plurality of said registration pins extending from the exterior surface of said cushion, said registration pins dimensioned to cooperatively engage axial passages communicating through said casing.
- 6. The protective helmet apparatus as defined in claim 3 wherein said means for attachment of said helmet casing to said mounting surface comprises a plurality of legs extending from the exterior surface of said helmet casing, the distal ends of said plurality of legs configured for cooperative engagement with a mount, said mount attachable to said mounting surface.
- 7. The protective helmet apparatus as defined in claim 3 further comprising:
- a chin aperture communicating through said front portion of said cushion, said chin aperture communicating between said interior surface and said exterior surface of said cushion, and

WO 01/76403

a nasai cavity defined by the perimeter of said chim

aperture and the wall surface of said chim aperture.

8. The protective helmet apparatus as defined in claim 7 further comprising a casing chin aperture in said casing front wall said casing chin aperture communicating between said casing interior surface and said casing exterior surface, said casing chin aperture shaped substantially similar in shape to said cushion chin aperture and positioned to align with said cushion chin aperture when said cushion is in said registered engagement with said helmet casing; and

said nasal cavity communicating from said interior surface of said cushion to said exterior surface of said casing thereby forming a tube passageway.

9. The protective helmet apparatus as defined in claim 8 wherein said cushion chin aperture and said cushion ocular aperture communicate to form a single cushion aperture communicating through said cushion,

said casing chin aperture and said casing ocular aperture communicating to from a single casing aperture substantially the same in shape as said single cushion aperture; and

said single cushion aperture and said single casing aperture are substantially in line when said cushion placed in said cooperative engagement with said helmet casing.

10. The protective helmet apparatus as defined in claim 3 further comprising a means for elevation of said helmet casing above said mounting surface.

- 11. The protective helmet apparatus as defined in claim 6 wherein said mount comprises
- a mounting plate, said mounting plate having an upper surface and a lower surface;

means of attachment of said lower surface to a determined position on said mounting surface; and

- a plurality of couplings affixed to said upper surface of said mounting plate in positions to register with said distal ends of said plurality of legs, said couplings dimensioned for cooperative engagement with the distal end of said legs, whereby said legs may be removably mounted to said couplings in a cooperative registered engagement therewith.
- 12. The protective helmet apparatus as defined in claim 3 wherein said cushions are in a kit of variably sized cushions to accommodate a variety of head sizes each of said cushions in said kit configured for cooperative registered engagement with said helmet casing whereby said combination of said helmet casing and said cushion may be fitted to a variety of different sized patients having different physical characteristics and may be assembled from said collection of interchangeable cushions.

13. The protective helmet apparatus as defined in claim 10 wherein said means for elevation of said helmet casing above said mounting surface comprises a plurality leg extensions chosen from a kit of said leg extensions of varying length, each of said leg extensions configured for cooperative engagement between the distal end of said legs and said couplings, whereby the resulting elevation of said helmet above said mounting surface may be adjusted using longer or shorter leg extensions.

- 14. The protective helmet apparatus as defined in claim 11 wherein said mount additionally comprises, a mirrored surface affixed to said mounting plate, thereby providing a means for upright individuals standing adjacent to said protective head apparatus to view the ocular area of the patients face reflected in the mirrored surface by looking downward at said mirrored surface.
- 15. The protective helmet apparatus as defined in claim 13 further comprising a means for angular adjustment of said mirrored surface in relation to said mounting plate, whereby the angle of said mirrored surface may be adjusted to the optimum angle for viewing said ocular area.
- 16. The protective helmet apparatus as defined in claim 13 further comprising a means for illumination, said means for illumination attached to one of said helmet casing or said mounting plate, said means for illumination positioned to

illuminate the face of said patient.

17. The protective helmet apparatus as defined in claim 3 further comprising:

means for heating the head of the patient attachable to said helmet casing.

- 18. The protective helmet apparatus as defined in claim 17 wherein said means for heating the head of a patient, is an electrical resistive heating element, attached to the interior surface of said helmet casing.
- 19. The protective helmet apparatus as defined in claim 15 herein said means for heating the head of a patient is an electrical resistive heating element mounted on a blanket which is attachable to one of said upper edges of said side walls, whereby said blanket may be folded over the patients head when said head is operatively occupying said protective helmet apparatus.
- 20. The protective helmet apparatus as defined in claim 3 wherein said helmet casing is constructed of substantially transparent material thereby affording a view into the ocular cushion aperture through the sidewall and front wall surfaces of the helmet casing.

21. The protective helmet apparatus as defined in claim 3 additionally comprising at least one tube passageway communicating through said helmet casing.

22. The protective helmet apparatus as defined in claim 3 wherein said helmet casing is adhered to said exterior surface of said cushion into a unitary structure.

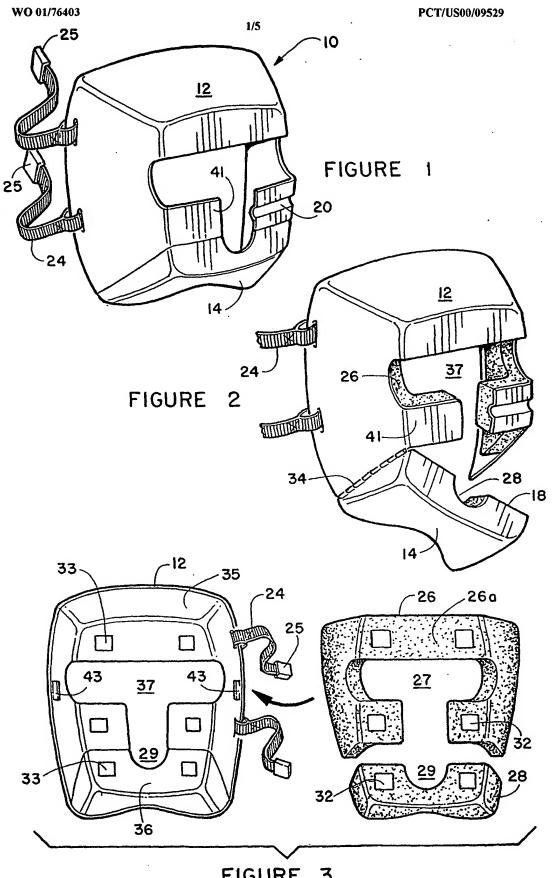
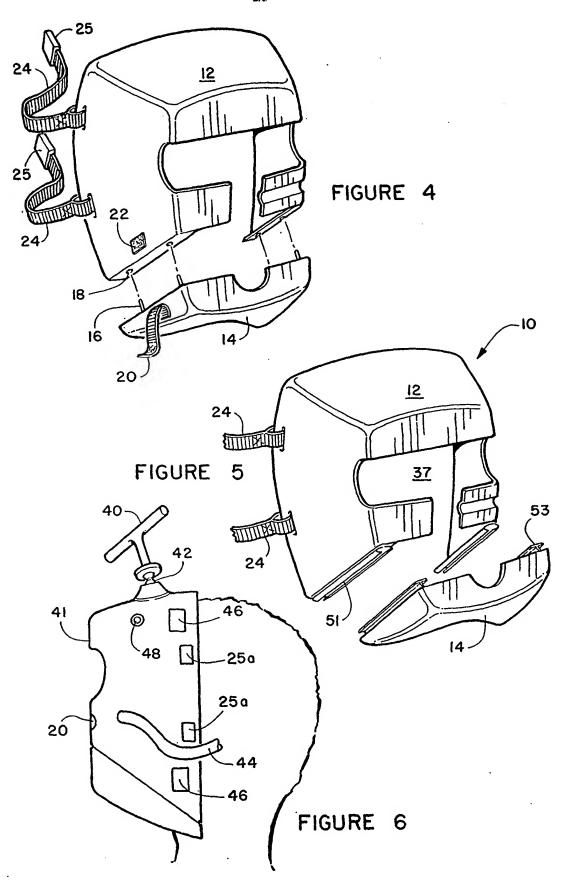
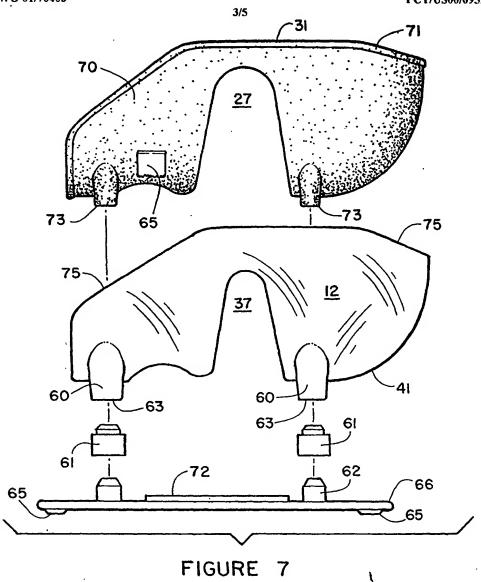
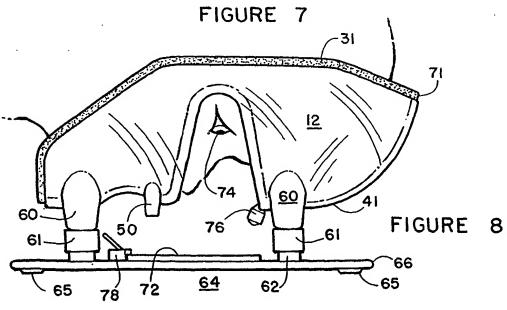
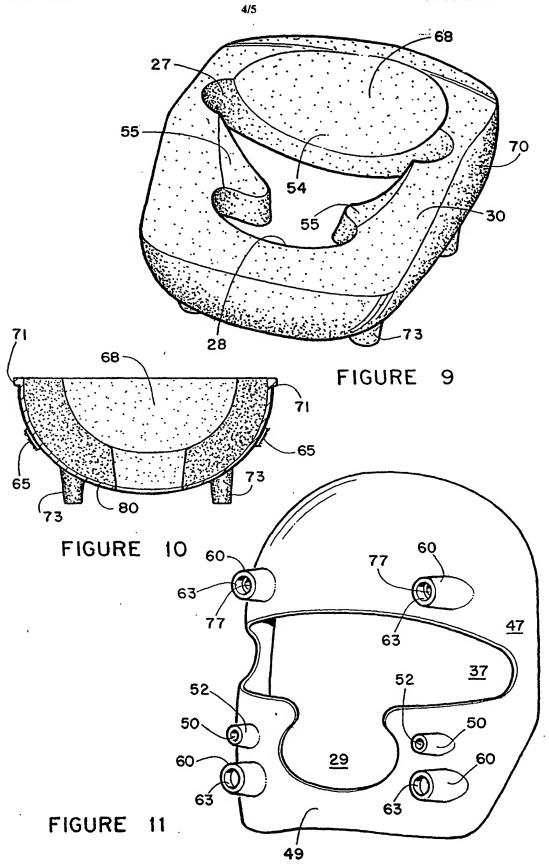


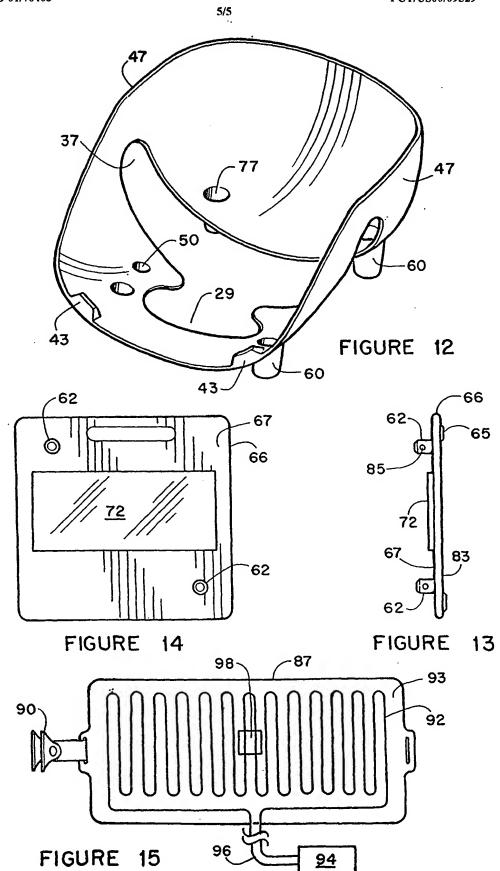
FIGURE 3











INTERNATIONAL SEARCH REPORT

International application No. PCT/US00/09529

IPC(7)	ASSIFICATION OF SUBJECT MATTER			
US CL	:A42B 3/00; A47C 20/00 :2/9; 5/636, 640; 128/851			
	to International Patent Classification (IPC) or to both nat	ional classification and IPC		
	LDS SEARCHED	ional classification and if C		
	documentation searched (classification system followed by	u planification au-t-t-V		
		y classification symbols)	•	
U.S. :	2/9, 422, 424; 5/622, 636, 640; 128/851			
Documenta	tion searched other than minimum do aumontation to the	A		
	tion searched other than minimum documentation to the ex	tent that such documents are included	in the fields searched	
Electronic (data base consulted during the international search (name			
	and one constitute during the international scarcii (hame	of data base and, where practicable,	search terms used)	
C. DOC	UMENTS CONSIDERED TO BE RELEVANT			
Category*	Citation of document, with indication, where appro-	priate, of the relevant passages	Relevant to claim No.	
X	US 4,752,064 A (VOSS) 21 June 1988, o	col. 3 lines 28-65.	1-4, 6-9, 21	
Y			17, 18	
v	110 4 504 050 4 (0000000000000000000000000	000		
X	US 4,504,050 A (OSBORNE) 12 March 1 3 line 19.	985, col. 2, line 51 to col.	1-4,10, 20, 22	
Y,P	US 5,771,514 A (WILHOIT) 30 June 1998, col. 5 lines 16-34. 17, 18			
A		1967 entire document		
••	US 3,337,883 A (ALLISON) 29 August 1967, entire document.		1-22	
Α	US 5,220,699 /. (FARRIS) 22 June 1993, entire document.		1-22	
]	
Further documents are listed in the continuation of Box C. See patent family annex.				
Special categories of cited documents: "T" later document published after the international filing date or priority				
	ocument defining the general state of the art which is not considered	date and not in conflict with the applic principle or theory underlying the inv	ation but cited to understand the	
	to be of particular relevance "X" document of particular relevance; the claimed invention cannot be			
	considered novel or cannot be considered to involve an inventive step			
cit	ted to establish the publication date of another citation or other ecial reason (as specified)		e claimed invention cannot be	
	considered to involve an inventive step when the document is			
"P" document published prior to the international filing date but later than				
the priority date claimed "&" document member of the same patent family				
Date of the	actual completion of the international search Da	te of mailing of the international sec	rch/Mati	
••		16 10	L ZUUU	
16 JUNE	2000	// X (~ I	
	Name and mailing address of the ISA/US Authorized officer			
Commissioner of Patents and Trademarks Box PCT				
Washington, D.C. 20231 MICHAEL A. NEAS				
Facsimile N	Facsimile No. (703) 305-3230 / Telephone No. (703) 308-0861			

VERTRAG ÜBE DIE INTERNATIONALE ZUS IMENARBEIT AUF DEM GEBIET DES PATENTWESENS

PCT

INTERNATIONALER VORLÄUFIGER PRÜFUNGSBERICHT

(Artikel 36 und Regel 70 PCT)

			•					
Aktenzeichen des Anmelders oder Anwalts M 9211 PCT		WEITERES VOR	siehe Mittellung über die Übersendung des Internationalen vorläufigen Prüfungsberichts (Formblatt PCT/IPEA/416)					
Internationales Aktenzeichen PCT/EP 03/10719		Internationales Anmelo 26.09.2003	ledatum (TagMonat/Jahr)	Prioritätsdatum (Tag/Monati 18.11.2002	Uahr)		
Inte	rnation	nale Pa	atentklassifikation (IPK) oder	nationale Klassifikation	and IPK			
	1G13		•					
100	nelder							
l .			1BH & CO. KG ET AL.					
1.	Die	ser in	ternationale vorläufige Pr	üfungsbericht wurde v	on der m	it der internatio	nalen vorläufigen Prüfung	
	Dea	unag	ten Behörde erstellt und	wird dem Anmeider ge	emäß Art	ikel 36 übermit	telt.	
E								
2.	Die	ser BE	ERICHT umfaßt insgesan	nt 5 Blätter einschließ	lich diese	es Deckblatts.		
	\boxtimes	Auß	lerdem liegen dem Berich Joder Zeichnungen, die a	nt ANLAGEN bei; dabe	ei handel	t es sich um Bla	ätter mit Beschreibungen,	Ansprüchen
		2011	orde vorgenommenen be	erichtigungen (siehe F	egel 70.	ericht zugrunde 16 und Abschni	liegen, und/oder Blätter m tt 607 der Verwaltungsrich	it vor dieser
		PCT	Г).		-			timileri zum
	Dies	se Anl	agen umfassen insgesan	nt 4 Blätter.				
				**				
3.	Dies	ser Be	ericht enthält Angaben zu	folgenden Punkten:				
	ı	Ø						
	, H		Grundlage des Besche	ids				
	" IH		Priorität					
	IV		Managed Sinh Stick	Gutachtens über Neul	neit, erfin	derische Tätigl	eit und gewerbliche Anwe	ndbarkeit
	V	⊠	Mangelnde Einheitlichk	•				
	V	М	gewerblichen Anwendb	g nach Regel 66.2 a)ii arkeit: Unterlagen und) hinsich I Erklären	tlich der Neuhe	it, der erfinderischen Tätig	keit und der
	VI		Bestimmte angeführte t	Jnterlagen	· Cillarai	ngen zur Statzu	ing dieser Feststellung	
	VII		Bestimmte Mängel der	•	duna			
	VIII		Bestimmte Bemerkunge		-	ına		
			ū			9	•	•
Datu	m der	Einreid	chung des Antrags		Datum	dor Corticatall	diana Davida	
		,	and good and ago		Datum	der Fertigstellung	dieses Berichts	
17.02.2004		40.00	0005					
		18.02.	2005					
Name und Postanschrift der mit der internationalen Prüfung Bevollmächtigter Bediensteter								
beau	beauttragten Behörde				Stisches Potemeny			
Europäisches Patentamt - P.B. 5818 Patentiaan 2 NL-2280 HV Rijswijk - Pays Bas Cametz, C								
	<u> </u>	i el Fax	. +31 70 340 - 2040 Tx: 31 6 :: +31 70 340 - 3016	551 epo nl		70 340-3434		
					161. +31	/ U .54U=3434		* A

INTERNATIONALER VORLÄUFIGER **PRÜFUNGSBERICHT**

Internationales Aktenzeichen PCT/EP 03/10719

1. Hinsichtlich der **Bestandteile** der internationalen Anmeldung (Ersatzblätter, die dem Anmeldeamt auf eine Aufforderung nach Artikel 14 hin vorgelegt wurden, gelten im Rahmen dieses Berichts als "ursprünglich eingereicht" und sind ihm nicht beigefügt, weil sie keine Änderungen enthalten (Regeln 70.16 und 70.17)):

	De:	schreibung, Seiten				
	3-6	į	in der ursprünglich eingereichten Fassung			
	1, 2	2	eingegangen am 10.05.2004 mit Schreiben vom 10.05.2004			
	An	sprüche, Nr.				
	1-7		eingegangen am 10.05.2004 mit Schreiben vom 10.05.2004			
	Zei	chnungen, Blätter				
	1/2-	-2/2	in der ursprünglich eingereichten Fassung			
2.	aie	internationale Anmel	e: Alle vorstehend genannten Bestandteile standen der Behörde in der Sprache, in der dung eingereicht worden ist, zur Verfügung oder wurden in dieser eingereicht, sofern sanderes angegeben ist.			
	Die ein(Die Bestandteile standen der Behörde in der Sprache: zur Verfügung bzw. wurden in dieser Sprache eingereicht; dabei handelt es sich um:				
		die Sprache der Übe (nach Regel 23.1(b)	ersetzung, die für die Zwecke der internationalen Recherche eingereicht worden ist).			
		die Veröffentlichung	ssprache der internationalen Anmeldung (nach Regel 48.3(b)).			
		die Sprache der Übe worden ist (nach Re	ersetzung, die für die Zwecke der internationalen vorläufigen Prüfung eingereicht gel 55.2 und/oder 55.3).			
3.	Hin: inte	sichtlich der in der int rnationale vorläufige	ernationalen Anmeldung offenbarten Nucleotid- und/oder Aminosäuresequenz ist die Prüfung auf der Grundlage des Sequenzprotokolls durchgeführt worden, das:			
		in der internationale	n Anmeldung in schriftlicher Form enthalten ist.			
		zusammen mit der in	nternationalen Anmeldung in computerlesbarer Form eingereicht worden ist.			
		bei der Behörde nac	hträglich in schriftlicher Form eingereicht worden ist.			
		bei der Behörde nac	hträglich in computerlesbarer Form eingereicht worden ist.			
		Die Erklärung, daß o Offenbarungsgehalt	las nachträglich eingereichte schriftliche Sequenzprotokoll nicht über den der internationalen Anmeldung im Anmeldezeitpunkt hinausgeht, wurde vorgelegt.			
		Die Erklärung, daß o Sequenzprotokoll er	lie in computerlesbarer Form erfassten Informationen dem schriftlichen itsprechen, wurde vorgelegt.			
4.	Auf	grund der Änderunge	n sind folgende Unterlagen fortgefallen:			
		Beschreibung,	Seiten:			
		Ansprüche,	Nr.:			
		Zeichnungen,	Blatt:			

INTERNATIONALER VORLÄUFIGER PRÜFUNGSBERICHT

Internationales Aktenzeichen

PCT/EP 03/10719

5. 🗆	Dieser Bericht ist ohne Berücksichtigung (von einigen) der Änderungen erstellt worden, da diese aus den angegebenen Gründen nach Auffassung der Behörde über den Offenbarungsgehalt in der ursprünglich	
		eingereichten Fassung hinausgehen (Regel 70.2(c)).

(Auf Ersatzblätter, die solche Änderungen enthalten, ist unter Punkt 1 hinzuweisen; sie sind diesem Bericht beizufügen.)

- 6. Etwaige zusätzliche Bemerkungen:
- V. Begründete Feststellung nach Artikel 35(2) hinsichtlich der Neuheit, der erfinderischen Tätigkeit und der gewerblichen Anwendbarkeit; Unterlagen und Erklärungen zur Stützung dieser Feststellung
- 1. Feststellung

ì

Neuheit (N)

Ja: Ansprüche 1-7

Nein: Ansprüche

Erfinderische Tätigkeit (IS)

Ja: Ansprüche 1-7

Nein: Ansprüche

Gewerbliche Anwendbarkeit (IA)

Ja: Ansprüche: 1-7

Nein: Ansprüche:

2. Unterlagen und Erklärungen:

siehe Beiblatt

Zu Punkt V

Begründete Feststellung hinsichtlich der Neuheit, der erfinderischen Tätigkeit und der gewerblichen Anwendbarkeit; Unterlagen und Erklärungen zur Stützung dieser Feststellung

1. Es wird auf die folgenden Dokumente verwiesen:

D1: WO 01/76403 A (MAZZEI WILLIAM) 18. Oktober 2001 (2001-10-18)

D2: US-B1-6 374 441 (BEGELL SUZANNE) 23. April 2002 (2002-04-23)

- Das Dokument D1 wird als nächstliegender Stand der Technik gegenüber dem 2. Gegenstand des Anspruchs 1 angesehen. Es offenbart (die Verweise in Klammern beziehen sich auf dieses Dokument) eine:
- Kopfstütze für eine Patientenlagerfläche mit einer starren Stützschale und einem 2.1 mit dieser lösbar verbindbaren Auflagepolster.
- von der sich der Gegenstand des Anspruchs 1 dadurch unterscheidet, daß die 2.2 Stützschale eine annähernd hufeisenförmige Gestalt hat mit einem zum Unterstützen des Hinterkopfes oder der Stirn bestimmten zentralen Abschnitt, dessen Auflagefläche mindestens annähernd kugelschalenförmig ist, und mit zwei einen Abstand voneinander aufweisenden Seitenabschnitten, deren Auflageflächen mindestens annähernd einer gemeinsamen Zylinderfläche angepaßt sind, deren Achse parallel zu einer zwischen den Seitenabschnitten verlaufenden Symmetrielinie der Kopfstütze ist, wobei an den Seitenabschnitten jeweils eine in Richtung auf den jeweils anderen Seitenabschnitt vorspringende Jochbeinstütze ausgebildet ist.
- Der Gegenstand des Anspruchs 1 ist somit neu (Artikel 33(2) PCT). 2.3
- Die mit der vorliegenden Erfindung zu lösende Aufgabe kann somit darin gesehen 3. werden, daß die Kopfstütze einerseits eine sichere Lagerung des Kopfes eines Patienten sowohl in der Bauchlage als auch in der Rückenlage desselben gewährleistet, und andererseits der Kopf des Patientes so weit wie möglich frei liegt, so daß der Operateur auch für Operationen am Kopf möglichst freien Zugang hat.

Die in Anspruch 1 der vorliegenden Anmeldung für diese Aufgabe vorgeschlagene Lösung beruht aus den folgenden Gründen auf einer erfinderischen Tätigkeit (Artikel 33(3) PCT) (Siehe auch in der Beschreibung, Seite 2, Zeilen 17 bis 26):

Die Stützschale ist dank der Hufeisenform relativ flach und bietet dennoch an den Für eine Auflage geeigneten Stellen des Kopfes, nämlich dem Schädel am Hinterkopf, der Stirn und den Wangenknochen eine sichere Abstützung. Die übrigen Partien des Kopfes bleiben weitgehend frei und sind daher auch für operative Eingriffe gut zugänglich.

Die in Dokument D1 beschriebene Kopfstütze hat die Form eines Helmes, welcher den Kopf mindestens zur Hälfte umschließt, wobei dieser Helm nur zur Aufnahme des Gesichtes, d.h. für eine Abstützung des Kopfes in der Bauchlage des Patienten bestimmt ist. Mit solcher Kopfstütze wird auch der Zugang zu den Kopfpartien für operative Eingriffe am Kopf stark eingeschränkt.

Die in Dokument D2 beschriebene Kopfstütze hat weder eine kugelschalenförmige Ausbildung des Mittelabschnittes des Hufeisens, noch zylindrisch geformte Auflageflächen der Seitenabschnitte des Hufeisens. Auch diese Kopfstütze ist nur dazu bestimmt, das Gesicht eines auf dem Bauche liegenden Patienten abzustützen.

Die Ansprüche 2 bis 7 sind vom Anspruch 1 abhängig und erfüllen damit ebenfalls 4. die Erfordernisse des PCT in bezug auf Neuheit und erfinderische Tätigkeit.

Kopfstütze für Patientenlagerfläche

Die Erfindung betrifft eine Kopfstütze für eine Patientenlagerfläche, insbesondere an Operationstischen, gemäß dem Oberbegriff des Anspruchs 1.

Aus der US 6,276,012 B2 ist eine Kopfstütze bekannt, die aus einem U-förmigen Teil und einem zwischen den U-Schenkeln liegenden plattenförmigen Abschnitt besteht. In der Rückenlage wird der Kopf des Patienten von beiden Teilen unterstützt. In der Bauchlage wird das plattenförmige Teil weggeklappt, so dass der Kopf des Patienten mit der Stirn auf dem Mittelsteg des U aufliegt und zumindest Mund und Nase des Patienten frei liegen. Die Kopfstütze insgesamt ist im wesentlichen eben ausgebildet und gepolstert. Sowohl in der Rückenlage als auch in der Bauchlage ist der Kopf seitlich abgestützt.

Aus der US-A-6,042,184 ist eine Ruheliege bekannt, die mit einer plattenförmigen Kopfstütze versehen ist. In der plattenförmigen Kopfstütze ist eine Öffnung ausgebildet, die von einem kreisringförmigen, nicht ganz geschlossenen Polster umgeben ist, das auf der Platte beispielsweise mit Druckknöpfen befestigt werden kann. Auch hier kann der Kopf einer Person nicht nur in der Rückenlage sondern auch in der Bauchlage abgestützt werden, wobei das Gesicht frei liegt. Die Kopfstütze ist jedoch nicht ausreichend an die menschliche Kopfform angepasst und ungeeignet, den Kopf eines Patienten während einer Operation, bei welcher der Patient längere Zeit regungslos gehalten werden muss, so abzustützen, dass der Patient keinen Schaden nimmt, beispielweise durch Druckstellen oder dergleichen.

Die WO 01/76403 A1 zeigt eine Kopfstütze, umfassend eine helmartig gewölbte Stützschale mit Öffnungen für die Augenpartie, Mund und Nase und ein Schaumstoffpolster mit entsprechenden Öffnungen zur Abstützung des Gesichts.

Die US 6,374,441 B1 zeigt eine Kopfstütze zur Abstützung des Gesichtes eines Patienten mit einem Brett, auf dem ein Schaumstoffpolster angeordnet ist, in das eine Kontur mit einem Hohlraum für die Augenpartie, Mund und Nase eingeschnitten ist.

Der Erfindung liegt die Aufgabe zugrunde, eine Kopfstütze der eingangs genannten Art anzugeben, die es ermöglicht, den Kopf in einer gewünschten Position so-



wohl in der Rückenlage als auch der Bauchlage des Patienten sicher für den Patienten schonend zu unterstützen.

Zur Lösung dieser Aufgabe hat die Stützschale der erfindungsgemäßen Kopfstütze eine annähernd hufeisenförmige Gestalt mit einem zum Unterstützen des Hinterkopfes oder der Stirn bestimmten zentralen Abschnitt, dessen Auflagefläche mindestens annähernd kugelschalenförmig ist , und mit zwei einen Abstand voneinander aufweisenden Seitenabschnitten, deren Auflageflächen mindestens annähernd einer gemeinsamen Zylinderfläche angepasst sind, deren Achse parallel zu einer zwischen den Seitenabschnitten verlaufenden Symmetrielinie der Kopfstütze ist, wobei an den Seitenabschnitten jeweils eine in Richtung auf den jeweils anderen Seitenabschnitt vorspringende Jochbeinstütze ausgebildet ist.

Die erfindungsgemäße Kopfstütze ist an die spezielle Form des menschlichen Kopfes angepasst und unterstützt den Kopf an den für eine solche Unterstützung geeigneten Flächen des Schädels, nämlich dem Hinterkopf oder der Stirn sowie den Wangenknochen. Durch die kugelschalenförmige bzw. zylindrische Wölbung der Abschnitte ist der Kopf so gebettet, dass er nicht nach der Seite umfallen kann. Die Jochbeinstützen an den Seitenabschnitten ermöglichen einerseits eine gute Unterstützung des Gesichtes in der Bauchlage des Patienten, wobei dennoch die Augenpartie sowie Mund und Nase für das Atmen bzw. die Beatmung sowie das Ansetzen einer Narkosemaske oder anderer Hilfsmittel frei belieben. Durch die anatomisch gerechte Form der erfindungsgemäßen Kopfstütze wird der Auflagedruck des Kopfes großflächiger über die Abschnitte der Kopfstütze verteilt, so dass die lokale Belastung vermindert wird und damit auch die längeren Operationen Druckstellen am Kopf, insbesondere im Gesicht vermieden werden können.

Im Gegensatz zu herkömmlichen Kopfstützen, bei denen zur seitlichen Abstützung des Kopfes das Polster sehr dick gemacht werden muss, d.h. der Kopf relativ weit in das Polster einsinkt, kann bei der erfindungsgemäßen Lösung wegen der anatomisch korrekten Form der Kopfstütze das Auflagepolster dünner gemacht werden. Die Stützschale ist zweckmäßigerweise



Ansprüche

- 1. Kopfstütze für eine Patientenlagerfläche mit einer starren Stützschale (10) und einem mit dieser lösbar verbindbaren Auflagepolster (12), dadurch gekennzeichnet, dass die Stützschale (10) eine annähernd hufeisenförmige Gestalt hat mit einem zum Unterstützen des Hinterkopfes oder der Stirn bestimmten zentralen Abschnitt (14), dessen Auflagefläche mindestens annähernd kugelschalenförmig ist, und mit zwei einen Abstand voneinander aufweisenden Seitenabschnitten (16), deren Auflageflächen mindestens annähernd einer gemeinsamen Zylinderfläche angepasst sind, deren Achse parallel zu einer zwischen den Seitenabschnitten (16) verlaufenden Symmetrielinie (20) der Kopfstütze ist, wobei an den Seitenabschnitten (16) jeweils eine in Richtung auf den jeweils anderen Seitenabschnitt (16) vorspringende Jochbeinstütze (18) ausgebildet ist.
- 2. Kopfstütze nach Anspruch 1, dadurch gekennzeichnet, dass die Stützschale (10) aus Kunststoff besteht.
- 3. Kopfstütze nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass das Auflagepolster (12) an seiner der Stützschale zugewandten Seite mindestens zwei Steckstifte (36) trägt, die zum Eingriff in die Stützschale (10) durchsetzende Bohrungen (40) bestimmt sind.
- 4. Kopfstütze nach Anspruch 3, dadurch gekennzeichnet, dass die Steckstifte (36) jeweils einen zylindrischen Schaft haben, der einen elastisch nachgiebigen Bund (38) mit einem gegenüber dem Bohrungsdurchmesser geringfügig größeren Außendurchmesser hat.
- Kopfstütze nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, dass sie entlang ihrer Symmetrielinie (20) in zwei spiegelbildlich gleiche Teilstützen (50) unterteilt ist.
- 6. Kopfstütze nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, dass die Kopfstütze bzw. jede Teilstütze mit einem Befestigungskloben (42) zu ihrer Halterung an einer Profilschiene verbunden ist.



- 2 -

7. Kopfstütze nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, dass an dem Außenrand jedes Seitenabschnittes (16) eine Öse (26) zur Befestigung eines zum Fixieren des Patientenkopfes auf der Kopfstütze bestimmten Bandes ausgebildet ist.

